EXHIBIT 1

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Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
C.D. California.
In re PAXIL LITIGATION
No. CV 01-07937 MRP.

Oct. 18, 2002.

Following grant of preliminary injunction enjoining manufacturer of prescription drug paraxetine from publication of statement in its nationally televised commercial that drug, under trade name "Paxil," was "non-habit forming," 2002 WL 1940708, manufacturer moved for reconsideration. The District Court, Pfaelzer, J., held that: (1) Food, Drug, and Cosmetic Act (FDCA) did not preempt state law claims, relating to control and regulation of advertisements by manufacturer; (2) doctrine of primary jurisdiction did not require deferral of preliminary injunction motion to Food and Drug Administration (FDA); but (3) consumers were not likely to succeed on merits of claim that advertisement was misleading.

Reconsideration granted, and preliminary injunction denied.

West Headnotes

[1] Consumer Protection ⚿36.1
92Hk36.1 Most Cited Cases

[1] States ⚿18.65
360k18.65 Most Cited Cases
Food, Drug, and Cosmetic Act (FDCA) did not preempt state law claims, relating to control and regulation of advertisements by manufacturer of prescription drug paraxetine; Congress did not intend, when it enacted the FDCA for purposes of protecting public health, to not only decline to provide private cause of action, but to also eliminate availability of common law state claims. Federal Food, Drug, and Cosmetic Act, § 1 et seq., as amended, 21 U.S.C.A. § 301 et seq.

[2] Health ⚿328
198Hk328 Most Cited Cases
Deferral, under primary jurisdiction doctrine, of preliminary injunction motion seeking to enjoin manufacturer of prescription drug paraxetine from publication of statement in its nationally televised commercial that drug, under trade name "Paxil," was "non-habit forming," to expertise of Food and Drug Administration (FDA) was not warranted; motion challenged determination of FDA and manufacturer that public was not likely to equate words "not habit forming" as used in direct to consumer advertisements with "no withdrawal symptoms," which was issue that was within one of district court's core competencies.

[3] Consumer Protection ⚿41
92Hk41 Most Cited Cases
Consumers of prescription drug paraxetine were not likely to succeed on merits of their claim that manufacturer's publication of statement in its nationally televised commercial that drug, under trade name "Paxil," was "non-habit forming," was misleading in violation of state law, as required for preliminary injunction enjoining publication of statement.

MEMORANDUM OF DECISION RE: Motion for Reconsideration of Order Granting Preliminary Injunction

PFAELZER, J.

I. INTRODUCTION

*1 On August 16, 2002, this Court entered an Order for Preliminary Injunction ("Order") in favor of Plaintiffs barring Defendant Glaxo Smithkline Beecham ("GSK") from continuing to air television commercials that make the claim that its prescription drug, Paxil, is "not habit forming."

In response, GSK filed a Motion to Suspend Preliminary Injunction Pending Appeal on August 19, 2002 and a Motion for Reconsideration on August 21, 2002. Additionally, at the Court's request, the United States Food and Drug Administration ("FDA") filed a supplemental brief on September 5, 2002. Oral argument by the parties and FDA was heard on October 8, 2002.

Having considered all the submitted papers as well as oral arguments, the Court GRANTS Defendant's Motion for Reconsideration and DENIES Plaintiffs' request for a preliminary injunction.

II. DISCUSSION

GSK and FDA have advanced a multitude of arguments in support of the Motion for Reconsideration, some of which are essentially repetitions of those advanced in prior filings. The Court deems only three of the arguments raised as requiring further comment.

A. Preemption

[1] FDA and GSK assert that the Court's ability to pass judgment upon prescription drug direct to consumer advertisements is limited by the Supremacy Clause of the United States Constitution. The comprehensive nature of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, they argue, when taken together with FDA's expertise, evidences a Congressional intent to preempt state law. Under their theory, control and regulation of these advertisements are within FDA's exclusive domain.

This argument is unpersuasive. To begin with, the parties reveal no case holding that the FDCA preempts state law either expressly or impliedly. If anything, FDA's and GSK's arguments run contrary to the grain of other decisions. *See, e.g., Knoll Pharm. Co. v. Sherman,* 57 F.Supp.2d 615 (N.D.Ill.1999); *Ohler v. Purdue Pharma. L.P.,* 2002 WL 88945 (E.D.La.2002); *Motus v. Pfizer,* 127 F.Supp.2d 1085, 1092 (C.D.Cal.2000).

Further, FDA's and GSK's position vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and GSK invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims. This position contravenes common sense, *cf. Medtronic, Inc. v. Lohr,* 518 U.S. 470, 487, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), and the Court declines the invitation.

B. Primary Jurisdiction

[2] The Court also finds deferral under the doctrine of primary jurisdiction inappropriate. While FDA's expertise in areas such as drug efficacy and side effects cannot be lightly challenged, the Court has not found it necessary to delve into any of those areas. The preliminary injunction does not challenge FDA's finding that Paxil is not clinically addictive nor does it involve labeling, inserts, or material directed to prescribing physicians.

**2 What it does challenge is FDA's and GSK's determination that the public is not likely to equate the words "not habit forming" as used in direct to consumer advertisements with "no withdrawal symptoms." The question of how members of the general public are likely to interpret (or misinterpret) a statement is within one of the courts' core competencies. Nothing here counsels otherwise.

C. Likelihood of Success on the Merits

[3] While the Court is unwilling to blindly accept FDA's ultimate determination here, it has given careful consideration to the extensive fact-finding engaged in by FDA with regard to Paxil and its approval of Paxil's advertisements. Specifically, FDA has now presented evidence to the Court regarding not only the internal review process involved in the advertisements in question, but also

its position that the advertisements are not misleading.

Once again, the Court reiterates that in resolving the question presented here, it is not required to decide, nor did it decide, whether Paxil is or is not habit forming. The Court is concerned only with whether in the specific direct to consumer advertisements before the Court, the statement that Paxil is not habit forming could be found to be misleading to consumers.

On this issue, the Court finds FDA's evidence persuasive such that it changes the Court's evaluation of Plaintiffs' likelihood of success on the merits to a degree dictating that the preliminary injunction be denied.

Not Reported in F.Supp.2d, 2002 WL 31375497 (C.D.Cal.)

Motions, Pleadings and Filings (Back to top)

• 2003 WL 22341240 (Trial Motion, Memorandum and Affidavit) Memorandum of Decision and Order Re: Motion for Class Certification Motion to Dismiss Non-California Plaintiffs (Aug. 29, 2003)

• 2003 WL 22331143 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Notice of Motion and Memorandum of Points and Authorities in Support of Second Motion for Class Certification (Jun. 23, 2003)

• 2003 WL 22331144 (Trial Motion, Memorandum and Affidavit) Defendant's Memorandum of Points and Authorities in Opposition to Plaintiffs' Renewed Motion for Class Certification (Jun. 23, 2003)

• 2003 WL 22331145 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Reply to Defendant GSK's Opposition to Second Motion for Class Certification (Jun. 23, 2003)

• 2003 WL 22014572 (Trial Motion, Memorandum and Affidavit) Memorandum of Decision and Order Re: Motion for Class Certification Motion to Strike Designations of Hanke and Robinson Motion to Strike Declaration of Karen A. Barth (Jan. 13, 2003)

• 2002 WL 32153481 (Trial Motion, Memorandum and Affidavit) Class Action Plaintiffs' Corrected Reply to Defendant's Opposition to Plaintiffs' Motion for Class Certification; Memorandum of Points and Authorities (Oct. 07, 2002)

• 2002 WL 32157255 (Trial Motion, Memorandum and Affidavit) Class Action Plaintiffs' Response to Brief of the United States of America and Opposition to GSK's Motion for Reconsideration (Sep. 23, 2002)

• 2002 WL 32153353 () (Aug. 16, 2002)

• 2002 WL 32153479 (Trial Motion, Memorandum and Affidavit) Class Action Notice of Motion and Motion for Preliminary Injunction; Memorandum of Points and Authorities in Support Thereof (Jul. 22, 2002)

• 2:01cv07937 (Docket)
(Sep. 14, 2001)

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Westlaw Attached Printing Summary Report for HASKINS,NATALIE 4587635

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EXHIBIT 2

Not Reported in F.Supp., 1996 WL 280810 (S.D.N.Y.), 1996-2 Trade Cases P 71,460

(Cite as: 1996 WL 280810 (S.D.N.Y.))

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Motions, Pleadings and Filings

United States District Court, S.D. New York.
SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P., Plaintiff,
v.
JOHNSON & JOHNSON-MERCK CONSUMER PHARMACEUTICALS CO., INC., Defendant.
JOHNSON & JOHNSON-MERCK CONSUMER PHARMACEUTICALS CO., INC., Plaintiff,
v.
SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P., Defendant.
No. 95 CIV. 7011 (HB), 95 CIV. 7688 (HB).

May 24, 1996.

Helene D. Jaffe, Irving Scher, Katherine A. Daniels , Weil, Gotshal & Manges, New York City, for SmithKline Beecham Consumer Healthcare, L.P.

Steven A. Zalesin, Jennifer L. Pariser, J. Andrew Stephenson, Patterson, Belknap, Webb & Tyler, New York City, for Johnson & Johnson-Merck Pharmaceuticals Co., Inc., Kathryn A. Meisel, Johnson & Johnson, of counsel.

OPINION

Baer, District Judge.

*1 This consolidated action concerns the lawfulness of various advertising claims made by Johnson & Johnson-Merck Pharmaceuticals Co., Inc. ("J&J-Merck") and SmithKline Beecham Consumer Healthcare, L.P. ("SmithKline Beecham") for their over-the-counter ("OTC") heartburn medications, PEPCID AC and TAGAMET HB, respectively. Each of the parties has come before this Court on several occasions to dispute the advertising claims proffered by the other and this Court has rendered a series of Orders and Opinions to resolve these disputes.

On February 15, 1996 the parties were before the Court to discuss four issues currently in dispute; (1) J&J-Merck requests that this Court hold SmithKline Beecham in contempt of one aspect of the Court's December 7, 1995 Order and Opinion; (2) SmithKline Beecham requests that the Court rescind the injunction contained in paragraph 2(a) of the Court's October 13, 1995 Order which enjoins SmithKline Beecham from claiming that TAGAMET HB has a faster onset of action than PEPCID AC; (3) J&J-Merck requests that the Court enjoin SmithKline Beecham's advertisements in which SmithKline Beecham claims that TAGAMET HB prevents heartburn in "half the time" of PEPCID AC; and (4) SmithKline Beecham requests that the Court enjoin J&J-Merck from further distribution of a direct mail advertisement alleging that it contains unlawful statements and may be in violation of the Court's Amended Order and Opinion of December 12, 1995. The parties submitted numerous affidavits, clinical studies and memorandums for the Court's review.

For the reasons which follow, J&J-Merck's motion for contempt is denied; SmithKline Beecham's request that the October 13, 1995 injunction be rescinded is granted; J&J-Merck's request that the Court enjoin SmithKline Beecham from further dissemination of the claim that TAGAMET HB prevents heartburn in "half the time" is denied; and SmithKline Beecham's request that the Court enjoin J&J-Merck from further distribution of a direct mail brochure is denied.

I. *Background*

Some familiarity with the underlying facts of this litigation is presumed. For an account of the development of each product and previously disputed claims, *see SmithKline Beecham Consumer Healthcare, L.P. v. Johnson &*

Johnson-Merck Consumer Pharmaceuticals Co., Inc., 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y.Oct. 13, 1995)(order granting preliminary injunction); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 906 F. Supp. 178 (S.D.N.Y. 1995); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y. Oct. 19, 1996)(order requiring SmithKline Beecham to disseminate letter); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y.Dec. 7, 1995)(order granting preliminary injunction), *modified, SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y. Dec. 12, 1995)(order granting preliminary injunction), *aff'd, SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co. Inc.*, -- F.3d --, 1996 WL 37325 (2d Cir. 1996); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y.Dec. 22, 1995)(order denying SmithKline Beecham's claims for relief of prior injunction); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688 (S.D.N.Y. Apr. 30, 1996)(order enjoining SmithKline Beecham from disseminating "Full Prescription Strength" advertisement). [FN1]

***2** There were four issues before the Court at the February hearing; (1) J&J-Merck's request that this Court hold SmithKline Beecham in contempt of the Court's December 7, 1995 Order and Opinion; (2) SmithKline Beecham's request that the Court rescind its injunction contained in paragraph 2(a) of the October 13, 1995 Order which enjoins SmithKline Beecham from claiming that TAGAMET HB has a faster onset of acid control than PEPCID AC; (3) J&J-Merck's request that the Court enjoin SmithKline Beecham's advertisements in which SmithKline Beecham claims that TAGAMET HB prevents heartburn in "half the time" of PEPCID AC; and (4) SmithKline Beecham's request that the Court enjoin J&J-Merck from further distribution of a direct mail brochure on the basis that it contains unlawful statements and may be in violation of the Court's Amended Order and Opinion of December 12, 1995.

a. *J&J-Merck's Motion for Contempt.*

At the initial hearing in this action J&J-Merck challenged SmithKline Beecham's claim that TUMS "starts working in seconds." Based on the evidence presented at the September hearing, the Court enjoined SmithKline Beecham:

> from representing in any advertisement or promotional communication on behalf of TAGAMET HB or TUMS that:
>
> ....
>
> (b) TUMS starts working within seconds, but this injunction does not preclude SmithKline Beecham from advertising that, based on head-to-head tests of stomach pH, TUMS starts to work fast and faster than PEPCID AC and has a faster onset of action than PEPCID AC.

Oct. 13, 1995 Order at ¶ 2(b).

Subsequent to the October Order, the question arose as to whether or not the Court intended that this provision apply to TUMS labelling and packaging. The Court discussed this issue in correspondence and phone conferences with the parties in late November of 1995. Pursuant thereto, the Court resolved this dispute in its December 7, 1995 Order, later amended on December 12, 1995. Paragraph 6 of the December 7, 1995 Order provides that:

> IT IS FURTHER ORDERED that neither party shall print or affix to their products labeling which contains any claim enjoined under the October 13, 1995 Order of this Court or this Order, nor shall either party continue to ship products bearing labels which contain an enjoined claim after the date of this Order. SmithKline Beecham and J&J-Merck shall replace any violative labeling as of the date of this Order. This injunction does not, however, require either party to recall from distribution any product to

> which labeling bearing an enjoined claim is already affixed so long as no such product is distributed after February 19, 1996.

Dec. 7, 1995 Ord. at ¶ 6.

J&J-Merck contends that SmithKline Beecham's interpretation of the Order is erroneous and that SmithKline Beecham deliberately violated paragraph 6 by continuing to ship TUMS product labelled with the enjoined claim subsequent to December 7, 1995. J&J-Merck interprets the language of the Order as requiring SmithKline Beecham to immediately cease shipments of TUMS product from its distribution center bearing enjoined labelling and which, as of that date, had not been distributed to consumers. *See* J&J-Merck Reply Memorandum of Law in Support of J&J-Merck's Motion for a Contempt Order at 3 [hereinafter "J&J-Merck's Reply Mem."].

***3** In support of their argument, J&J-Merck referred to 500 pages of distribution records produced by SmithKline Beecham which list the numbers of TUMS bottles distributed from SmithKline Beecham warehouses and distribution centers to retail outlets subsequent to December 12, 1995. Tr. at 5. In addition, J&J-Merck referenced the deposition of Steven L. Burton, the SmithKline Beecham executive in charge of compliance with the December Order. At his deposition, Mr. Burton confirmed that SmithKline Beecham had continued to ship TUMS product bearing the enjoined labelling after December 12, 1995 and further stated that he could not "give you an assurance that no product is continuing to go out the door, because I believe we still have until February 19 to do that." *See* Burton Dep. at 89; *see also* J&J-Merck Reply Mem. at 3.

SmithKline Beecham maintains that it complied with the December Order and that it called the Court for a clarification of what it regarded to be an ambiguity in paragraph 6. Tr. at 9-10. SmithKline Beecham interpreted paragraph 6 to prohibit it from further affixing enjoined labelling to TUMS products after December 7, 1995, but to permit the company to deplete its remaining inventory of TUMS products labeled prior to December 7, 1995 so long as any stock was depleted by February 19, 1996. Tr. at 9-10.

b. *Onset of Action.*

Pursuant to the September Hearing and October 13, 1995 Order, this Court enjoined SmithKline Beecham from representing in any advertisement that:

> TAGAMET HB has a faster onset of action for heartburn than PEPCID AC, in terms of acid control, unless SmithKline Beecham conducts an appropriate study that supports its claims and provides said study and proposed copy to the Court on 72 hours notice to Johnson & Johnson-Merck Consumer Pharmaceuticals Co.

Oct. 13, 1995 Order at ¶ 2(a). SmithKline Beecham requested relief from the injunction contained in paragraph 2(a) on January 23, 1996. [FN2]

In February, SmithKline Beecham submitted to the Court two head-to-head fasted clinical studies, a head-to-head analysis of blood serum concentration levels of both drugs in fasted subjects, a separate head-to-head fed gastric acidity study, a study measuring the time to onset of relief for PEPCID AC, and a head-to-head study measuring the time to onset of acid control of the active ingredients of the relevant drugs when injected intravenously. *See* SmithKline Beecham Exs. 105, 106, 111, 113, 115.

In addition, SmithKline Beecham submitted two letters in support of their position, and affidavits from Dr. Jon I. Isenberg, Dr. Malcolm Robinson, and Dr. Neena Washington. *See e.g.,* Jan. 23, 1996 & Feb. 13, 1996 ltrs. from SmithKline Beecham to Judge Baer; Isenberg Aff.; Robinson Aff. and Washington Aff. Drs. Robinson and Washington, as well as Dr. Karl Peace, also testified at the February hearing. In accordance with the Court's procedures, SmithKline Beecham submitted proposed copy of an advertisement to the Court which contains two claims enjoined under the October 13, 1995 Order. *See* Ex. A. [FN3]

1. SmithKline Beecham's fasted studies.

***4** SmithKline Beecham submitted two head-to-head, crossover clinical studies that compared the effects of TAGAMET HB and PEPCID AC on intragastric pH in fasted subjects. Exs. 105, 106; [hereinafter "fasted studies"]. One study was conducted by Pharmakinetics Laboratories, Inc. and included 36 subjects and the other by Harris Laboratories, Inc. included 48 subjects. Isenberg Aff. ¶ 21. Each measured the gastric pH level of the subject's stomach by use of a pH electrode placed in the stomach. *Id.* The Pharmakinetics study also measured the blood plasma concentration levels of the drugs over the duration of the study. *Id.*

SmithKline Beecham used three different endpoints to determine the speed at which each product worked from the point of dosing; (1) time to first statistically significant decrease; (2) time to 90% reduction in stomach acidity; and (3) time to 40% reduction in gastric acidity. Isenberg Aff. ¶ 22, Exs. E, F, G. In each of these three categories, TAGAMET HB reached a faster onset of action than PEPCID AC. TAGAMET HB reached a statistically significant decrease in stomach acidity in 32.5 minutes while PEPCID AC reached the same point in 42.5 minutes; TAGAMET HB reduced 90% of gastric acid in 52.5 minutes and PEPCID AC achieved the same result in 62.5 minutes; and TAGAMET HB reduced 40% of gastric acid within 32.5 minutes whereas it took PEPCID AC 47.5 minutes to reduce the same level of acid. Tr. 111-12; Isenberg Aff. ¶¶ 19-29, Ex. E (Table 1), F, G (Table 1); Peace Aff. ¶¶ 11, 13-17, 21-26.

SmithKline Beecham acknowledges that it excluded non-responders [FN4] from the second and third portions of its testing, i.e. the time to 90% and 40%, respectively, in acid reduction, but that non-responders were included in the calculation of time to statistically significant decrease in stomach acid, the point at which the medication began to reduce stomach acid by a statistically significant margin. Tr. at 113; Peace Supp. Aff. ¶ 4. SmithKline Beecham reanalyzed the data and determined that when non-responders were included in the subject pool, TAGAMET HB still had a faster onset of action than PEPCID AC. Tr. 106-08; SmithKline Beecham Ex. 119. [FN5]

J&J-Merck challenge SmithKline Beecham's fasted studies as insufficient to prove that TAGAMET HB has a faster onset of action than PEPCID AC. J&J-Merck asserts that the studies provided contain only pooled data and that when the studies were evaluated individually, the results of the studies were not statistically significant. [FN6] According to J&J-Merck, the Harris study included data from one subject which did not respond to the medication and the Pharmakinetics study included data from six non-responders. J&J-Merck also introduced a report from Pharmakinetics which states that there was "no statistically significant difference in the time of onset of effect (decrease in ion concentration) after cimetidine or famotidine." Tr. 64-65; J&J-Merck Ex. 125. In addition, J&J-Merck elicited testimony on cross-examination from SmithKline Beecham's expert, Dr. Robinson, that neither the Harris study, nor the Pharmikinetics study, individually showed a statistically significant difference in onset between the two drugs. Tr. at 66. [FN7]

***5** J&J-Merck further challenged the significance of SmithKline Beecham's studies on the basis that they excluded non-responders from the data pool and that this exclusion biased the studies in favor of TAGAMET HB. J&J-Merck Pre-hearing Mem. at 5-6; J&J-Merck Post-hearing Mem. at 10-12; Peace Supp. Aff. ¶ 4. J&J-Merck asserts that 10% of the subjects tested did not respond to TAGAMET HB but did respond to PEPCID AC and that the non-responders were excluded from the data pool, thereby skewing the data in favor of TAGAMET HB. J&J-Merck Post-hearing Mem. at 10-11. According to J&J-Merck, once the data from the non-responders is added back into the data pool, there is no statistically significant difference between the two drugs and the mean time to onset was faster for PEPCID AC than TAGAMET HB. J&J-Merck Ex. 21 at 41-42.

J&J-Merck further criticized the validity of SmithKline Beecham's studies by arguing that the results were distorted by the way in which testers measured the pH levels of stomach acid. Tr. at

144-45. [FN8] J&J-Merck further opined that any decrease in gastric acidity was meaningless and that a patient would not even begin to feel any relief of symptoms at the point at which SmithKline Beecham claims that TAGAMET HB provides a 90% reduction in stomach acidity. Tr. at 145-46.

2. SmithKline Beecham's fed study.

SmithKline Beecham also submitted the results of a fed study conducted by Inveresk Research International and which involved 50 subjects. SmithKline Beecham Ex. 113. The fed study was virtually analogous to the fasted studies discussed above, except that the fed study measured the onset of action of TAGAMET HB, PEPCID AC and ZANTAC 75 and the subjects ate a meal two hours prior to ingesting the medications. *Id.* The results of the study indicate that when non-responders are excluded, the time to a 40% reduction in stomach acidity was 61.1 minutes for TAGAMET HB and 84.6 minutes for PEPCID AC and the time to a 90% reduction in stomach acidity was 79.8 minutes for TAGAMET HB and 104.6 minutes for PEPCID AC. *Id.* When non-responders were added back into the pooled data, the time to a 40% reduction in gastric acidity was 57.5 minutes for TAGAMET HB and 97.5 minutes for PEPCID AC and the time to a 90% reduction was 82.5 minutes for TAGAMET HB and 102.5 minutes for PEPCID AC. SmithKline Beecham Ex. 113. Each of these results were statistically significant. Tr. at 108-09; Peace Supp. Aff. ¶ 4.

J&J-Merck again criticized the fed study on many of the same grounds discussed in relation to the fasted studies, *infra.* In particular, J&J-Merck challenged the way in which SmithKline Beecham excluded non-responders and argued that, by excluding non-responders, the study detected only minimal differences which were not statistically significant. Schiller Decl. ¶ 23; Holt Decl. ¶ 22; Ivey Decl. ¶ 25; Cohen Decl. ¶ 18; Connor Decl. ¶ 20; Decktor Decl. ¶ 23.

3. SmithKline Beecham's blood serum analysis.

***6** SmithKline Beecham submitted a head-to-head analysis of blood concentration levels of the subjects throughout the testing period. SmithKline Beecham Ex. 107; Spitznagel Aff., Exs. E-I. [FN9] It argues that this study is relevant to determine the onset of each medication because the efficacy of H_2 blockers is dependant upon the degree of their presence in the bloodstream. *See* n.1, *infra.* The study determined that the mean time to the first peak, the point at which the onset of action of one medication was statistically significant when compared with the other, was 56 minutes for TAGAMET HB and 80 minutes for PEPCID AC. SmithKline Beecham Ex. 107; Spitznagel Aff. ¶ 10.

Not unexpectedly, J&J-Merck criticized SmithKline Beecham's blood analysis as meaningless. They contend that there are more molecules in cimetidine, the active ingredient in TAGAMET HB, than famotidine, PEPCID AC's active ingredient, Tr. at 133, and therefore, molecules of TAGAMET HB have a greater opportunity to bond with H_2-receptor antagonists than molecules of PEPCID AC. Further, J&J-Merck challenges the study concluding that it fails to measure the strength of the two medications and that a single molecule of PEPCID AC is stronger than its TAGAMET HB counterpart. Tr. at 153. J&J-Merck's expert, Dr. Freston, testified that although there are more TAGAMET HB molecules which can be detected in a subject's blood stream, the molecules of PEPCID AC have a greater effect and the onset of effect of the two drugs is the same. Tr. at 152.

4. Other studies submitted.

While the studies discussed above were the principal focus of testimony on the onset of action issue, the parties submitted additional studies for the Court to review. SmithKline Beecham submitted a intravenous injection study in which the active ingredients in the two medications were injected into subjects intravenously and their onset of action measured. SmithKline Beecham Ex. 111. The study detected a 71% difference in onset in favor of TAGAMET HB. SmithKline Beecham Ex. 111; Washington Aff. ¶¶ 11-14; Washington Supp.

Aff. ¶ 14. J&J-Merck criticized this study as an invalid comparison because the medications were injected into persons suffering from ulcers, used agents to inhibit acid secretion, and measured the pH of the stomach lining. Schiller Decl. ¶ 22; Holt Decl. ¶ 21.

J&J-Merck submitted two fasted onset of action studies to the Court which measured the intra-gastric pH levels of subjects. J&J-Merck Studies 082 and 083; SmithKline Beecham Ex. 114; Decktor Decl. Ex. E. In study 082, researchers concluded that the relative onset of action for TAGAMET HB and PEPCID AC was essentially the same. *Id.* SmithKline Beecham challenged J&J-Merck's studies and produced evidence that, when reanalyzed, J&J-Merck's studies tended to support SmithKline Beecham's argument that TAGAMET HB has a faster onset of action. Peace Supp. Aff. ¶ 9; Washington Supp. Aff. ¶ 19; SmithKline Beecham Ex. 133.

c. *TAGAMET HB's Prevention Claim.*

*7 J&J-Merck seeks to preliminarily enjoin SmithKline Beecham from the further dissemination of advertisements which make the claim that TAGAMET HB prevents heartburn in half the time of, or in less time than PEPCID AC. *See* Ex. A (attached). [FN10] J&J-Merck alleges that this claim is literally false and that studies prove that PEPCID AC and TAGAMET HB both work to prevent heartburn at the same rate when taken 30 minutes prior to eating a meal. *See* Decktor decl. at ¶¶ 36-37. Specifically, J&J-Merck claims that these advertisements convey the false message to consumers "that TAGAMET HB works faster than PEPCID AC to prevent heartburn, [and] that only TAGAMET HB (and not PEPCID AC) can prevent heartburn when taken 30 minutes prior to eating a meal". *See* Vernon decl. at ¶ 5.

To support its contention, J&J-Merck submitted two studies, 080 and 081, to prove that when taken 30 minutes prior to a meal, PEPCID AC can prevent heartburn. J&J-Merck Exs. 1, 2; Decktor Decl. ¶ 47. [FN11] The results show that PEPCID AC was significantly superior to the placebo, and a greater percentage of subjects who took PEPCID AC experienced either no heartburn symptoms or less severe symptoms when compared to those who took the placebo. J&J-Merck Ex. 1 at 5-7; J&J-Merck Ex. 2 at 5-7. J&J-Merck further claims that SmithKline Beecham's Dr. Robinson testified that PEPCID AC works to relieve symptoms of heartburn in 30 minutes. Tr. at 87.

In response, SmithKline Beecham asserts that the advertisements are literally truthful and are based solely on the labelling directions for each product. The FDA approved label for TAGAMET HB states: "[f]or prevention of symptoms brought on by consuming food and beverages, take 2 tablets with water 30 minutes before eating a meal you expect to cause symptoms". *See* Daniels Aff., Ex. A. Conversely, the FDA approved label for PEPCID AC states: "[f]or prevention of symptoms brought on by consuming food and beverages swallow 1 tablet 1 hour before eating a meal you expect to cause symptoms". *Id.* at Ex. B. Accordingly, SmithKline Beecham argues that the faster prevention of symptoms claim is truthful and that the advertisements are not misleading.

While J&J-Merck does not dispute what the labels on each product state, J&J-Merck maintains that the labels are simply the result of the Food and Drug Administration's drug approval process and are not indicative of the speed at which each drug begins to relieve the symptoms of heartburn. Decktor decl. at ¶ ¶ 41-42. To obtain FDA approval for PEPCID AC, J&J-Merck submitted two studies which showed that patients who took famotidine had fewer and less severe heartburn symptoms than those who had taken a placebo by a statistically significant margin. *Id.* at ¶ 39. The FDA approved PEPCID AC based on these studies and, consistent with the dosing regimen used in the studies, approved labelling for PEPCID AC which states that patients should take 1 tablet "1 hour before eating a meal you expect to cause symptoms." *Id.* at ¶ 39. [FN12] Similarly, to obtain FDA approval for TAGAMET HB SmithKline Beecham submitted studies to the FDA which provided evidence of TAGAMET HB's effectiveness when used according to the dosage regimen of the studies. *Id.* at ¶ 41.

d. *J&J-Merck's Direct Mail Brochure.*

***8** SmithKline Beecham asks this Court to enjoin a direct mail brochure which J&J-Merck distributed to households across the country and which includes a free sample of PEPCID AC. *See* Ex. B to this Opinion. The brochure is a four page document which asserts on the front page that: "Now you can control heartburn *before* it starts." *Id.* SmithKline Beecham alleges that the brochure violates this Court's December 7, 1995 Order, as amended December 12, 1995, which preliminarily enjoined J&J-Merck from disseminating advertising on behalf of PEPCID AC containing the claim "Only PEPCID AC has proven that it can prevent heartburn and acid indigestion," or that "TAGAMET HB and/or other H_2 blockers do not prevent heartburn and acid indigestion." Dec. 12, 1995 Order at ¶ 4(b).

SmithKline Beecham further charges that the direct mailer contains claims which violate section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). At the hearing, the Court's focus was limited to three aspects of the brochure: (1) the claim that PEPCID AC is more effective for heartburn than TAGAMET HB and TUMS; (2) the comparison, in chart form, between PEPCID AC, TAGAMET HB and TUMS; and (3) comparisons between PEPCID AC and TUMS products.

1. The "more effective" claim.

SmithKline Beecham challenges that J&J-Merck's "Satisfaction Guarantee" language which appears on the back of the brochure, as being a comparative claim "that PEPCID AC is more effective for heartburn than TAGAMET HB or TUMS." *See* Ex. B at 4. The specific text at issue states:

> The PEPCID AC Satisfaction Guarantee
> We're so sure you'll feel that PEPCID AC is more effective for heartburn than TAGAMET HB or TUMS, we're guaranteeing it! If one PEPCID AC tablet doesn't work better for your heartburn than two TAGAMET HB or TUMS tablets, Johnson & JohnsonMerck will refund your full purchase price. No questions asked.
> Strong promise? Strong medicine. Here's what PEPCID AC can do
> Just one tablet controls acid for 9 hours through the night. [FN**]
> PEPCID AC can actually *prevent* heartburn.
> PEPCID AC carries no drug interaction warnings.
> Those are the facts guaranteed. But the real test is how PEPCID AC works for you. So try it and see.

See Ex. B at 4. SmithKline Beecham contends that the three bullet points which appear below the "Satisfaction Guarantee" provide support for J&J-Merck's comparative claim and that two of the three bullet point statements, the second and third, are facially false.

SmithKline Beecham contends that the first of the two bullet point statements, that "PEPCID AC can actually *prevent* heartburn" violates paragraph 4(b) of the December 12, 1995 Order of this Court. As stated above, paragraph 4(b) enjoins J&J-Merck from making the claim that "only PEPCID AC can prevent heartburn." SmithKline Beecham challenges that the second of the two bullet point statements, that "PEPCID AC carries no drug interaction warnings" does not relate to PEPCID AC's efficacy and could mislead consumers. *See* Kazak Aff., Exhs. E and F.

***9** J&J-Merck contends that the "Satisfaction Guarantee" is not a comparative claim but rather is an invitation to consumers to try PEPCID AC and determine for themselves that it is more effective at controlling their heartburn and acid indigestion than TAGAMET HB or TUMS. Vernon Decl. at ¶¶ 12- 13. J&J-Merck also contends that even if the "Satisfaction Guarantee" does make an efficacy claim, the claim is true and is supported by both witnesses for J&J-Merck and SmithKline Beecham. *Id.* at ¶ 13; *see also* Tr. at 143 (testimony of SmithKline Beecham witness Dr. Washington that PEPCID AC is more effective in terms of its potency and the fact that it binds to a drug receptor more closely and stays bound longer than TAGAMET HB); Tr. at 153 (testimony of J&J-Merck witness Professor Freston that PEPCID "clearly is more powerful ... [[[e]very one of the PEPCID molecules that hits the target is so much more powerful, it asserts its effect at a higher

concentration.")

J&J-Merck further contends that the second bullet point statement, "PEPCID AC can actually *prevent* heartburn," which SmithKline Beecham has charged as violative of paragraph 4(b) of the December 12, 1995 Order should not be enjoined. J&J-Merck argues that the brochure does not contain a claim that "only" PEPCID AC can prevent heartburn nor a claim that "TAGAMET HB cannot prevent heartburn." Vernon Decl. at ¶ 8. In addition, J&J-Merck argues that the third claim, "PEPCID AC carries no drug interaction warnings," is a legitimate claim as the FDA does not require J&J-Merck to place a warning on its product packaging that PEPCID AC interacts with other drugs. Vernon Decl. at ¶ 10(d).

2. The comparison chart.

SmithKline Beecham also challenged a chart contained in the direct mail brochure which compares PEPCID AC to TAGAMET HB and TUMS. *See* Ex. B at 2. The chart lists four reasons and corresponding check marks to tell consumers why "PEPCID AC is better than TAGAMET HB or TUMS in these important ways." *Id.* SmithKline Beecham challenges two of the four statements in the chart; "Just *one* tablet per dose" and "No drug interaction warnings." SmithKline Beecham asks that this Court enjoin J&J-Merck making either of these claims in a comparative advertisement which makes qualitative or quantitative claims that PEPCID AC is better than TAGAMET HB or TUMS.

In response, J&J-Merck argues that both of the claims challenged, as well as the two which SmithKline Beecham does not challenge, are true. Vernon Decl. at ¶¶ 10(c), (d). Packaging for PEPCID AC states that the recommended dose for a person who suffers from heartburn or acid indigestion is one tablet. *Id.* at ¶ 10(c). J&J-Merck argues that neither TAGAMET HB nor TUMS can claim that only one tablet is recommended per dose. [FN13] Additionally, J&J-Merck claims that PEPCID AC is the only one of the three products which is not required to place drug interaction warnings on its packaging or package inserts. Vernon Decl. at ¶ 10(d). In contrast, the FDA requires TAGAMET HB to place drug interaction warnings on both its packaging and its package inserts and TUMS product packaging advises consumers that "[a]ntacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional." *Id.*

3. Comparisons between PEPCID AC and TUMS products.

***10** SmithKline Beecham requests that this Court enjoin J&J-Merck from continued dissemination of advertisements which contain the claim that, "One PEPCID AC tablet controls stomach acid for 9 hours through the night. To neutralize the same amount of stomach acid, you would have to take 13 TUMS tablets." *See* Ex. B at inside page. SmithKline Beecham challenges that this is an establishment claim which is unsupported and confusing to consumers because the statement does not specify which TUMS product of the three available is being compared with PEPCID AC. In addition, SmithKline Beecham contends that none of the three TUMS products available recommend that a person consume as many as 13 tablets in a 9 hour period.

In response J&J-Merck states that the advertisement refers only to TUMS. J&J-Merck argues that because the ad mentions TUMS and not TUMS EX or TUMS ULTRA, it is clear to the consumer which product the ad discusses. J&J-Merck further contends that this claim is supported by two daytime acid control studies which compare PEPCID AC directly with TUMS. Vernon Decl. at ¶ 10(a). Lastly, J&J-Merck argues that this claim is not based on a comparison of nighttime acid control for PEPCID AC and daytime acid neutralization for TUMS.

II. *Discussion*

Section 43(a) of the Lanham Act prohibits the dissemination of false and misleading advertising in interstate commerce. 15 U.S.C. § 1125(a). A court

may enjoin a claim pursuant to the provisions of the Lanham Act if the claim is material and likely to influence a consumer's purchasing decision. *See Skil Corp. v. Rockwell Int'l Corp.*, 375 F. Supp. 777, 782-83. An ad which is literally false may be enjoined without reference to the impact of the advertisement on the public. *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (citations omitted). A court may enjoin an ad which is implicitly false, however, only when the court determines that the ad is misleading, confusing or deceiving as tested by public reaction. *Coca-Cola Company v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982).

When an advertisement makes an "establishment claim" or in other words, a product claim of superiority, the claim must be supported by a reliable survey or test. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992) (to prove establishment claim is explicitly or implicitly false, plaintiff must show that tests did not establish proposition for which they were cited). Additionally, the study or survey must be statistically significant and support the claim for which it stands. *McNeil-P.P.C.,Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549-50 (2d Cir. 1991) (plaintiff conclusively demonstrated that studies supporting superiority claim were not statistically significant); *American Home Prods. v. Johnson & Johnson*, 577 F.2d 160, 169 n. 19 (2d Cir. 1978) (court disregarded non-statistically significant studies); *Coors Brewing Co. v. Anheuser-Busch Cos.*, 802 F. Supp. 965, 973-74 (S.D.N.Y. 1992) (court disregarded consumer survey because it was not statistically significant); *Philip Morris Inc. v. Loew's Theatres, Inc.*, 511 F. Supp. 855, 857-58 (S.D.N.Y. 1980) (advertising based on consumer preference is false when supporting study lacks statistical significance). Each of the four items before the Court at the February 15th hearing is addressed below in the order in which they were presented.

a. *J&J-Merck's Motion for Contempt is Denied.*

***11** "A court may hold a party in civil contempt ... if there is a clear and unambiguous order, noncompliance is proven clearly and convincingly, and 'the defendant has not been reasonably diligent and energetic in attempting to accomplish what was ordered.'" *Drywall Tapers, Local 1974 v. Local 530 of Operative Plasterers and Cement Masons Int'l,* 889 F.2d 389, 394 (2d Cir. 1989) (*quoting Powell v. Ward,* 643 F.2d 924, 931 (2d Cir.), *cert. denied,* 454 U.S. 832 (1981)), *cert. denied,* 494 U.S. 1030 (1990). J&J-Merck contends that the *Drywell Tapers* standards are satisfied here and that the Court should hold SmithKline Beecham in civil contempt of its December 7, 1995 Order. For the reasons which follow, I disagree.

As I stated at the February hearing, SmithKline Beecham's interpretation of paragraph 6 conforms to what this Court intended when it originally drafted the provision. Tr. at 10. It is this Court's view that paragraph 6 permitted SmithKline Beecham to deplete their existing warehouse stock of TUMS products bearing enjoined labelling provided that the product was labelled prior to December 7, 1995 and no shipment took place after February 19, 1996. *Id.* It is also this Court's view that this same paragraph prohibited SmithKline Beecham from attaching to TUMS product any label bearing an enjoined claim subsequent to the date of the Order. *Id.* Accordingly, J&J-Merck has failed to demonstrate clearly and convincingly that SmithKline Beecham failed to comply with this Court's Order.

Similarly, J&J-Merck failed to demonstrate that SmithKline Beecham has not acted diligently and energetically to comply with the December Order; in fact, this Court finds the contrary to be true. SmithKline Beecham submitted affidavits prior to the February hearing and made oral representations to the Court on February 15, 1996 that it has complied with the provisions of paragraph 6. *See* Tr. at 10; *see also* Burton Aff. at ¶¶ 5-7; Daniels Aff. at ¶¶ 18-20. In addition, SmithKline Beecham assured the Court that no TUMS product bearing a label with an enjoined claim would be shipped from its distribution facilities subsequent to February 19, 1996. Tr. at 10-11. For these reasons J&J-Merck's application that this Court find SmithKline Beecham in civil contempt of paragraph

6 of the December 7, 1995 Order is denied.

b. *The Injunctive Relief Contained in Paragraph 2(a) of the October 13, 1995 Order is Rescinded.*

Subsequent to the September 13, 1995 preliminary injunction hearing in this action, the Court determined that SmithKline Beecham's advertising claim, "TAGAMET HB has a faster onset of action for heartburn than PEPCID AC", was false. *SmithKline Beecham,* 906 F. Supp. at 188. Accordingly, on October 13, 1995 this Court enjoined SmithKline Beecham from representing in any advertisement that:

> TAGAMET HB has a faster onset of action for heartburn than PEPCID AC, in terms of acid control, unless SmithKline Beecham conducts an appropriate study that supports its claims and provides said study and proposed copy to the Court on 72 hours notice to Johnson & Johnson-Merck Consumer Pharmaceuticals Co.

***12** Oct. 13, 1995 Order at ¶ 2(a).

At the September hearing, the Court heard testimony from J&J-Merck's experts, Drs. Freston and Laird, and reviewed the studies submitted by both J&J-Merck and SmithKline Beecham on the relative onset of action of both drugs. *SmithKline Beecham,* 906 F. Supp. at 186-88. The Court concluded that, based on the evidence presented, SmithKline Beecham's claim that TAGAMET HB had a faster onset of action than PEPCID AC was facially false. *Id.* at 188-89. The Court further determined that to support this claim, SmithKline Beecham must conduct a head-to-head fasted study which measured the onset effects of the two drugs and which demonstrated that the claim is true. *Id.* at 188. In accordance with the procedure outlined in the October Order, for SmithKline Beecham to be relieved of this injunction, the Order required a head-to-head study as described, or comparable evidence which supports the claim to be presented to the Court on 72 hours notice to J&J-Merck.

SmithKline Beecham now presents a head-to-head fasted study, as well as additional support, to the Court and requests that the Court lift the injunction contained in paragraph 2(a) of the October Order. The issue before the Court is whether or not SmithKline Beecham's studies prove that TAGAMET HB has a faster onset of action than PEPCID AC. Having reviewed the studies and listened to much testimony, both direct and cross, I conclude that SmithKline Beecham's studies support their onset of action claim.

The head-to-head fasted study submitted by SmithKline Beecham demonstrates to my satisfaction that TAGAMET HB began to stop the production of gastric acid at a statistically significant faster rate than PEPCID AC. SmithKline Beecham Ex. 120. I was also convinced on the basis of the evidence presented that the exclusion of non-responders from the data pool did not impact on the threshold measurement which calculated the time from dosing to the first statistically significant change in gastric pH. Tr. at 113, 106-07; Peace Supp. Aff. ¶ 4, Ex. D. Thus, whether or not non-responders were included in the data pool is irrelevant. In short, TAGAMET HB achieved a statistically significant difference faster than PEPCID AC and has a faster onset of action than PEPCID AC.

SmithKline Beecham supplemented its head-to-head fasted studies with additional relevant data collected in a fed study, a blood serum analysis, and an intravenous injection study. Each of these additional studies confirms SmithKline Beecham's findings in the head-to-head fasted studies. The results of the studies when viewed together with the head-to-head fasted studies discussed *infra,* provide adequate additional support to SmithKline Beecham's advertising claim. J&J-Merck submitted its own fasted studies to the Court. I find that they failed to disprove SmithKline Beecham's claim related to the onset of action of the two medications.

The law requires that SmithKline Beecham be able to support any superiority claim made in advertisements for TAGAMET HB with a reliable and statistically significant study, *Quaker State Oil Refining Co. v. Burmah-Castrol, Inc.,* 504 F. Supp. 178, 181 (S.D.N.Y. 1980); SmithKline Beecham has satisfied this requirement. For that reason and in

accordance with the Court's Order dated May 24, 1996, the injunction contained in paragraph 2(a) of the October Order is hereby rescinded. The Court understands that any SmithKline Beecham advertising disseminated on behalf of TAGAMET HB which contains the claim that TAGAMET HB has a faster onset of action than PEPCID AC, or a similar claim, will include a disclaimer which expressly states that a faster onset of action does not necessarily mean faster symptomatic relief.

c. *TAGAMET HB's "prevention claim" is not enjoined.*

***13** J&J-Merck challenges that SmithKline Beecham's television and print advertisements in which SmithKline Beecham claims that TAGAMET HB prevents heartburn when taken 30 minutes prior to a meal while PEPCID AC's labelling recommends that heartburn sufferers take it one hour before a meal are literally false. Pursuant to the provisions of the Lanham Act and the case law in this Circuit, the Court can enjoin an ad which is literally false without reference to the advertisement's impact on the public. *McNeil-P.C.C.,Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (citations omitted). However, a court may enjoin an ad which is implicitly false only if it determines that the ad is misleading, confusing or deceiving as tested by public reaction. *Coca-Cola Company v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982). Thus, the issue before the Court is whether or not SmithKline Beecham's advertising that TAGAMET HB prevents heartburn in half the time of PEPCID AC is false and misleading.

For an over-the-counter medication to be sold in this country, it must obtain approval from the FDA not only of the medication but also its packaging and any package inserts. Decktor Decl. ¶ 38. To support claims made on proposed packaging and in package inserts, manufacturers are required to submit sufficient support which proves to the FDA that the medication is safe and effective in accordance with package and labelling directions. *Id.* Both of the medications at issue here submitted studies to the FDA which supported their respective claims of efficacy and safety. The FDA, after careful analysis of the studies and the proposed packaging, returned to the manufacturers the approved labelling for each product.

Each of the claims J&J-Merck challenges is based on the package labelling approved by the FDA for both drugs. Although it is clear that the FDA did not determine on its own volition that PEPCID AC must be taken one hour prior to a meal to be effective in reducing the symptoms of heartburn, the FDA presumably relied on the studies which support this claim when it approved package labelling for PEPCID AC. Decktor Decl. ¶¶ 39-42. Accordingly, for this Court to now state that J&J-Merck can advertise that PEPCID AC begins to relieve the symptoms when taken 30 minutes prior to a meal, or conversely, to enjoin SmithKline Beecham from claiming that TAGAMET HB works faster than PEPCID AC on the basis of package labelling, would substitute this Court's discretion for that of the FDA in approving package labelling for over-the-counter medications.

J&J-Merck characterizes the label difference as "meaningless", J&J-Merck Post-hearing Mem. at 28, and cites Studies 080 and 081 as proof that PEPCID AC works to relieve the symptoms of heartburn when taken 30 minutes prior to a provocative meal. *Id.* at 27-28. The Court finds that J&J-Merck's studies support the contention that PEPCID AC begins to work when taken 30 minutes prior to a provocative meal. However, the advertisements J&J-Merck challenges do not make the claim that TAGAMET HB works faster than PEPCID AC on the basis of scientific studies. Rather, the claim is premised on package labelling [FN14] and, in that regard, is neither facially false nor misleading.

d. *J&J-Merck's Direct Mail Brochure is Not Enjoined.*

***14** The Lanham Act prohibits the dissemination of false and misleading advertising in interstate commerce. 15 U.S.C. § 1125(a). A court may enjoin a claim pursuant to the provisions of the Lanham Act if the claim is material and likely to

influence a consumer's purchasing decision. *See Skil Corp. v. Rockwell Int'l Corp.,* 375 F. Supp. 777, 782-83. SmithKline Beecham challenges that J&J-Merck's direct mail brochure violates this Court's December 7, 1995 Order because it contains the claim "PEPCID AC can actually *prevent* heartburn". In addition, SmithKline Beecham claims that the brochure is false and misleading in violation of the Lanham Act, 15 U.S.C. § 1125(a). [FN15] Having reviewed the challenged brochure as well as the briefs submitted on this point, I find that the brochure does not contain the same claim enjoined in the December 7, 1995 Order and that the remaining claims in the brochure are not false and misleading, and conclude SmithKline Beecham's request that this Court enjoin J&J-Merck's brochure must be denied.

In paragraph 4(b) of the Court's December 7, 1995 Order, J&J-Merck was enjoined from disseminating advertising on behalf of PEPCID AC that claimed " *Only* PEPCID AC has proven that it can prevent heartburn and acid indigestion," or that "TAGAMET HB and/or other H_2 blockers do not prevent heartburn and acid indigestion." Dec. 12, 1995 Order at ¶ 4(b) (emphasis added) [hereinafter the "only" claim]. In the brochure currently before the Court, J&J-Merck offers consumers a "Satisfaction Guarantee" which is supported by three bullet point comments, the second of which is that "PEPCID AC can actually *prevent* heartburn." While SmithKline Beecham contends that this claim is analogous to the "only" claim enjoined in December, it is the Court's view that these two claims are different.

The "only" claim is an exclusivity claim -- i.e. it singles out PEPCID AC from the group of products available to heartburn sufferers -- and excludes any other products as able to provide relief to heartburn sufferers. In contrast, J&J-Merck now makes a claim to support its contention that consumers would be satisfied with PEPCID AC because it [like other products in the same category] prevents heartburn. SmithKline Beecham argues that when this claim is viewed in context with the Satisfaction Guarantee, it is a comparative claim which is false on its face. The Court concludes, however, that the "Satisfaction Guarantee" is not a comparative claim that PEPCID AC is more effective than TAGAMET HB or TUMS. Accordingly, this claim does not violate the Court's December 7, 1995 Order.

Turning to the remaining claims in the brochure, the Court finds that they are neither false nor misleading. J&J-Merck proffered evidence sufficient to prove that the claims comparing PEPCID AC with TUMS are true. Vernon Decl. ¶ ¶ 10(a), (b), (c); Decktor Decl. ¶ 54; J&J-Merck Exs. J, K. J&J-Merck produced two daytime studies which directly compare PEPCID AC with TUMS, Vernon Decl. ¶ 10(a), PEPCID AC can control acid for up to 9 hours at night yet TUMS cannot, Vernon Decl. ¶ 10(b), the recommended dose of PEPCID AC is one tablet, unlike the recommended 1-2 tablet dose of TUMS, Vernon Decl. ¶ 10(c), and the FDA does not require PEPCID AC to carry drug interaction warnings on its packaging whereas the TUMS packaging contains a warning that antacids may interact with certain prescription drugs. Vernon Decl. ¶ 10(d). Conversely, J&J-Merck is not required by the FDA to list drug interaction warnings and the recommended dose of PEPCID AC is one tablet.

***15** While SmithKline Beecham challenged the validity of J&J-Merck's two studies regarding TUMS and PEPCID AC, I conclude that J&J-Merck's claims are not such that they would mislead consumers. Each of the claims made within the brochure is true. Accordingly, under the law of this Circuit, SmithKline Beecham is not entitled to enjoin J&J-Merck's direct mail brochure.

III. *Conclusion*

For the foregoing reasons, J&J-Merck's motion for contempt is DENIED; SmithKline Beecham's request that the injunction in paragraph 2(a) of October 13, 1995 to be rescinded is GRANTED; J&J-Merck's request that the Court enjoin SmithKline Beecham from further dissemination of the claim that TAGAMET HB prevents heartburn in "half the time" is DENIED; and SmithKline Beecham's request that the Court enjoin J&J-Merck from further distribution of a direct mail brochure is DENIED.

SO ORDERED.

Exhibit A

[spokesperson shows stomach graphic which contains some stomach acid]	SPOKESPERSON Excess stomach acid. It can cause heartburn and acid indigestion.
[spokesperson talks on screen]	Now people who suffer from heartburn and acid indigestion have a choice of at least two medicines which can control stomach acid at its source.
[spokesperson shows Tagamet HB and Pepcid AC packages]	Tagamet HB and Pepcid AC, they're not the same.
[spokesperson talks on screen] Onset of acid control does not imply onset of symptom relief.	Tagamet HB actually starts controlling stomach acid faster than Pepcid AC. [super: Onset of acid control does not imply onset of symptom relief.]
[spokesperson talks on screen] Onset of acid control does not imply onset of symptom relief.	So Tagamet HB starts to reduce stomach acid in less time than Pepcid AC. [super. Onset of acid control does not imply onset of symptom relief.]
[package visual of Tagamet HB] Advanced Relief of Heartburn	Tagamet HB, Advanced Relief of Heartburn.

Exhibit B
TABULAR OR GRAPHIC MATERIAL SET AT THIS POINT IS NOT DISPLAYABLE

FN1. Essentially, the two products which are the focus here, TAGAMET HB and PEPCID AC, are over-the-counter heartburn medications known within the trade as H_2-blockers. These drugs were previously available only as the prescription strength medications TAGAMET and PEPCID. Heartburn is a condition which results from the reflux of gastric acid up into the esophagus. H_2 -blockers work pharmacologically, i.e. after a patient ingests the recommended dose, the tablets dissolve in the stomach and pass into the small intestine where they are absorbed into the bloodstream. The medications then pass through the bloodstream to the H_2 histamine receptors in the stomach wall where the two bind together to block the production of gastric acid. This effort, in combination with the natural workings of the stomach, decreases acid levels and results in a higher gastric pH. When the acidity of the stomach is reduced, the pH level is increased.

FN2. "Onset of action" refers to the rate of speed by which each drug begins to control and reduce the production of acid within a subject's stomach. "Onset of action" is not commensurate with symptomatic relief.

FN3. SmithKline Beecham requests this Court's permission to run an advertisement which claims that "TAGAMET HB actually starts controlling stomach acid faster than PEPCID AC" and "TAGAMET HB starts to reduce stomach acid in less time than PEPCID AC." *See* Ex. A. The proposed advertisement also contains a disclaimer which states "Onset of acid control does not imply onset of system relief." *Id.*

FN4. J&J-Merck contends that if the non-responders were incorporated into the data, SmithKline Beecham's results would not be as favorable. Non-responders are individuals who did not benefit from ingesting one or both of the medications being tested.

FN5. Dr. Peace testified on direct that when the non-responders were added back into the data pool, "the median time to response is 57.5 minutes when the subjects were on TAGAMET and 65 minutes when the subjects were on PEPCID.... And the median time to 40 percent reduction when the subjects were on TAGAMET is 35 minutes and when on PEPCID was 47.5 minutes. The lower one, staying with that, has an associated P value of .0248, which is certainly statistically significant." Tr. at 107.

FN6. In this context, a statistically significant study is one in which TAGAMET HB begins to work faster than PEPCID AC by a significant margin.

FN7. On cross-examination Dr. Robinson testified as follows:
Question: "... is it now your testimony that you did not know that there were these two separate reports of PharmacoKinetics [sic] and Harris which did not show a difference between the drugs, is that right?"
....
Answer: "The answer is these obviously are not -- these are not saying -- these reports do not say that TAGAMET is slower than PEPCID AC. They merely fail to show a difference." Tr. at 66.

FN8. A J&J-Merck expert, Dr. Freston testified that SmithKline Beecham converted the pH scale to the hydrogen ion, or H+ scale and that "the direct conversion is not literal and not valid.... [T]he only reason one does something like

this is to magnify trivial differences." Tr. at 144-45.

FN9. In the Pharmakinetics fasted study, two milliliters of venous blood samples were drawn from each of the subjects prior to dosing and 10, 20, 30, 40, 50, 60, 75, 90, 105, 120, 180 and 240 minutes after dosing. The plasma concentration over time was analyzed to determine the time to first peak of plasma concentration and the time to 90% reduction in gastric acidity for the two medications. Spitzenagel Aff. ¶¶ 8-9.

FN10. In one of the challenged television commercials, two women are seated at a table looking over a menu. One woman tells the other that all of the items she would like to eat cause her to suffer from heartburn. This same woman then states that "it's too late to take my PEPCID AC, the package says to prevent heartburn, you have to take it an hour before eating." A superimposed written statement appears at the bottom of the frame and states: "Take 1 hour before meals you know will cause heartburn." The second woman then responds: "An hour?! You don't have to wait that long .... Try my TAGAMET HB. The label says it takes half the time of your PEPCID." A superimposed statement appears at the bottom of the frame and states: "Take 30 minutes before meals you know will cause heartburn." At the conclusion of the commercial an announcer states: "TAGAMET HB. Advanced prevention of heartburn in half the time." Again, a superimposed statement appears at the bottom of the commercial, "According to Labelling." SmithKline Beecham has aired similar commercials in support of TAGAMET HB. Each is a pre-meal setting and refers to the package labelling for each product.
The challenged print advertisement is similar to its television counterparts. The print advertisement states: "TAGAMET HB prevents heartburn when taken 30 minutes before eating or drinking.... No antacid, not even MYLANTA, or MAALOX, can claim to prevent heartburn at all.... And PEPCID AC's labelling tells you to take it a full hour before mealtime to prevent heartburn. Sometimes you can't plan that far ahead."

FN11. Studies 80 and 81 used identical protocols. In both studies patients (233 patients were enrolled in Study 80 and 246 were enrolled in Study 81) received either PEPCID AC or a placebo 30 minutes prior to a provocative meal known to cause heartburn symptoms. Each study was a double-blind, randomized, placebo-controlled, multi-center, parallel study. Patients were randomly assigned to test groups. After patients intested the medication and ate a provocative meal, patients were required to state whether or not they had heartburn and, if so, to rate the severity of their symptoms on a 5-point scale (4=excellent; 3=good; 2=fair; 1=poor; 0=ineffective). Decktor Decl. ¶¶ 43-46.

FN12. It should be noted that the FDA approved the label for PEPCID AC on the basis of the dosing regimen used in the two studies submitted by J&J-Merck. The FDA did not determine that taking PEPCID AC less than 1 hour prior to a meal would lessen its effectiveness. *See* Decktor decl. at ¶ 40.

FN** Duration of acid control does not imply duration of symptom relief.

FN13. The Court notes that the packaging for TAGAMET HB recommends heartburn or acid indigestion sufferers take two tablets for relief and the recommended dosing instructions for each of the three TUMS products, TUMS, TUMS EX, and TUMS ULTRA, is 1-2 tablets.

FN14. Both the television and print advertisements refer directly to package labelling and the television commercials contain a superimposed statement that all claims are based on package labelling.

FN15. SmithKline Beecham claims that the brochure is false and misleading because it contains the claim that PEPCID AC is more effective for heartburn than TAGAMET HB and TUMS; it compares, in chart form, PEPCID AC, TAGAMET HB and TUMS and it compares PEPCID AC and TUMS products.

Not Reported in F.Supp., 1996 WL 280810 (S.D.N.Y.), 1996-2 Trade Cases P 71,460

Motions, Pleadings and Filings (Back to top)

- 1:95cv07688 (Docket)
  (Sep. 05, 1995)
- 1:95cv07011 (Docket)
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EXHIBIT 3

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Not Reported in F.Supp.2d

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Not Reported in F.Supp.2d, 1998 WL 883469 (D.Del.), 1999-1 Trade Cases P 72,457

(Cite as: 1998 WL 883469 (D.Del.))

United States District Court, D. Delaware.
In re WARFARIN SODIUM ANTITRUST LITIGATION
No. MDL 98-1232-SLR.

Dec. 7, 1998.

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MEMORANDUM OPINION

ROBINSON, District J.

I. INTRODUCTION

***1** This litigation consists of five actions consolidated here by the Judicial Panel on Multidistrict Litigation pursuant to 28 U.S.C. § 1407(a). Plaintiff Barr Laboratories, Inc. ("plaintiff") originally filed its suit on March 9, 1998 in the Southern District of New York against defendant DuPont Merck Pharmaceutical Company ("defendant"). [FN1] (D.I. 1 (98 Civ. 1695)) Plaintiff is a generic pharmaceutical manufacturer incorporated in New York with a principal place of business in Pomona, New York. (D.I. 1, ¶ 5 (98 Civ. 1695)) Defendant is a partnership between E.I. DuPont de Nemours & Co. (a Delaware corporation with a principal place of business in Wilmington, Delaware) and Merck & Co. (a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey). (D.I. 1, ¶ 6 (98

Civ. 1695)) Defendant manufactures and distributes pharmaceuticals and has its principal place of business in Wilmington, Delaware. (D.I. 1, ¶ 6 (98 Civ. 1695))

> FN1. By letter dated July 30, 1998, the court was informed that defendant had changed its name to DuPont Pharmaceuticals Company.

Class plaintiffs Kusnerik and Altman filed class action complaints in the District of Delaware, (D.I. 1 (C.A.97-659)(C.A.97-670)) while class plaintiffs Tischler and Steckel [FN2] each filed class action suits against defendant in the Southern District of Florida (D.I. 1 (98-178-Civ.)) and the Western District of Pennsylvania (D.I. 1 (98-697)), respectively (collectively, "class plaintiffs"). Class plaintiffs purport to represent a class of more than 1.8 million persons who purchased Coumadin for personal use at any time during the period beginning on or about July 28, 1997 to the present. (D.I. 1, ¶ 6 (C.A.97-659))

> FN2. Class plaintiff Steckel sued defendants DuPont Pharmaceutical Company, E.I. DuPont de Nemours & Company, and Merck & Company, Inc. For purposes of this memorandum opinion, these defendants shall be referred to in the singular.

In this action, plaintiff and class plaintiffs allege that defendant engaged in unlawful monopolization and attempted monopolization in violation of § 2 of the Sherman Act. 15 U.S.C. § 2. Plaintiff also asserts claims against defendant founded on § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), § 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c), the New York General Business Law, N.Y. Gen. Bus. L. §§ 349 and 350, and common law product disparagement and tortious interference with prospective business advantage. Plaintiff and class plaintiffs seek trebled damages under § 4 of the Clayton Act. Class plaintiffs also seek injunctive relief under § 16 of the Clayton Act. Additionally, class plaintiffs Tischler and Steckel allege that defendant's actions violated various state laws.

Currently before the court is defendant's motion to dismiss plaintiff's claims and class plaintiffs' claims for failure to state a claim upon which relief can be granted. Fed.R.Civ.P. 12(b)(6). The court has federal question jurisdiction pursuant to 28 U.S.C. § § 1331 and 1337. The court also has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. For the reasons that follow, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted.

II. BACKGROUND

***2** The following facts are taken from plaintiff's and class plaintiffs' complaints and, for purposes of this motion to dismiss, are accepted as true. This suit arises from plaintiff's attempt to market a generic version of defendant's successful and profitable blood thinner known as "Coumadin." Coumadin is the brand name for defendant's formulation of warfarin sodium--an anticoagulant agent, taken orally, prescribed for patients suffering from thrombosis, embolisms, and other blood-clotting disorders. (D.I. 1, ¶¶ 1, 9 (98 Civ. 1695)) Warfarin sodium (either in generic form or as the active ingredient in Coumadin) is classified as a Narrow Therapeutic Index ("NTI") drug because too little of it can lead to stroke or cardiac arrest and too much of it can cause internal bleeding. (D.I. 1, ¶ 19 (98 Civ. 1695)) Consequently, treating physicians must carefully monitor patients taking either Coumadin or generic warfarin sodium.

Although the patent protection for Coumadin expired on April 2, 1962, Coumadin has dominated the oral anticoagulant market for over thirty years. (D.I. 1, ¶¶ 11, 12 (98 Civ. 1695)) In fact, until plaintiff's generic warfarin sodium tablets were introduced in 1997, no equivalent product competed with Coumadin for several years. (D.I. 1, ¶¶ 11, 69 (98 Civ. 1695)) Defendant's annual Coumadin sales are approximately $500 million. (D.I. 1, ¶ 24 (C.A.97-659)) According to class plaintiffs, the cost of Coumadin has escalated 300% to 400% in the past ten years. (D.I. 1, ¶ 25 (C.A.97-659))

Plaintiff and class plaintiffs allege that defendant, anticipating a loss of market share to plaintiff's cheaper warfarin sodium tablets, [FN3] "implemented a multifaceted attack against generic substitutes generally and [plaintiff's] product specifically, the cumulative effect of which has been to raise [plaintiff's] costs to enter the anticoagulant market and to hinder [plaintiff's] ability to penetrate the market effectively." (D.I. 1, ¶ 16 (98 Civ. 1695); D.I. 1, ¶ 33 (C.A.97-659)) Plaintiff and class plaintiffs contend that defendant engaged in allegedly anticompetitive tactics in order to preserve its monopoly in the oral anticoagulant market. Class plaintiffs claim that, due to defendant's anticompetitive activities, they have paid inflated prices for Coumadin. (D.I. 1, ¶ 51 (C.A.98-178))

> FN3. Plaintiff notes in its complaint that
> [t]he introduction of a generic alternative to a brand name product typically results in significant reduction in the brand name product's market share within the first year. The high level of a generic drug's market penetration is due to its lower cost, generic substitution laws, and preferred status in third-party reimbursement plans.
> (D.I. 1, ¶ 15 (98 Civ. 1695))

More specifically, in May 1995 plaintiff filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to manufacture and distribute generic warfarin sodium tablets. (D.I. 1, ¶ 21 (98 Civ. 1695)) In October of 1996, defendant filed a Petition for Stay with the FDA asking it to postpone approval for all generic warfarin sodium products pending the adoption of stricter bioequivalence standards. [FN4] (D.I. 1, ¶ 22 (98 Civ. 1695)) In its Petition for Stay, defendant argued that the FDA's current bioequivalence standards were inadequate to assure the bioequivalence of Coumadin with other generic warfarin sodium drugs. Defendant asked the FDA to adopt a stricter "individual" bioequivalence standard, rather than an "average" standard, to determine whether generic warfarin sodium products were bioequivalent to Coumadin. [FN5]

> FN4. Bioequivalence "means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 29 C.F.R. § 320.1(e) (1998).
>
> FN5. Plaintiff and class plaintiffs characterize this Petition for Stay as "baseless" and designed specifically to inflict competitive injury on plaintiff by forcing it to conduct time-consuming and costly studies before it could enter the oral anticoagulant market. (D.I. 1, ¶ 68 (98 Civ. 1695); D.I. 1, ¶ 33 (C.A.97-659))

***3** The FDA denied defendant's petition, stating that it was

> in the process of considering individual bioequivalence testing for all generic drugs. At this time, however, it is neither reasonable nor in the interest of the public to impose such testing standards on generic applicants because the approach has not been fully developed and current methods are effective in establishing bioequivalence between drug products.

(D.I. 1, ¶ 29 (98 Civ. 1695)(citing letter from FDA to defendant of 3/25/97, at 3)) The FDA has since issued a request for public comment on a preliminary draft proposal that "recommends that the individual bioequivalence approach be used by sponsors of ANDAs ... to assess bioequivalence between a generic and a listed drug ." 62 Fed.Reg. 67880, 67881 (Dec. 17, 1997). [FN6]

> FN6. In ruling on a motion to dismiss, a court may consider only the allegations contained in the complaint, exhibits attached thereto, and matters of public record. *See* 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1357 (2d ed.1990). Where, as here, the parties have provided the court with undisputedly authentic regulatory

> documents, the court may consider them in reviewing a motion to dismiss. *See City of Pittsburgh v. West Penn Power Co.,* 147 F.3d 256, 259 (3d Cir.1998); *see also Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.,* 998 F.2d 1192, 1196 (3d Cir.1993).

During the same period of time, defendant filed a petition with the United States Pharmacopeial Convention, Inc. ("USP"), urging the USP to adopt Coumadin's narrow content uniformity specifications (which are stricter than those the USP currently requires) as the industry standard for all warfarin sodium drugs. [FN7] (D.I. 1, ¶ 24 (98 Civ. 1695)) The USP publishes the official compendium of pharmaceuticals in the United States, and listing in the USP is essential to the acceptance of a pharmaceutical product by the medical community. (D.I. 1, ¶ 24 (98 Civ. 1695)) The USP rejected the petition.

> FN7. Plaintiff further alleges that defendant's petitioning of the USP to narrow the content uniformity specifications for warfarin sodium tablets was "an obvious attempt to impose stricter regulations on a new competitor" designed to thwart plaintiff's entry into the oral anticoagulant market. (D.I. 1, ¶¶ 23, 24 (98 Civ. 1695))

Plaintiff began marketing its warfarin sodium tablets on July 25, 1997. (D.I. 1, ¶ 26 (98 Civ. 1695)) Despite its unsuccessful petitioning efforts with the FDA and the USP, defendant allegedly issued communications setting forth its position that Coumadin is safer and more efficacious than plaintiff's warfarin sodium tablets. It is asserted by plaintiff that:

- Defendant revised its "Couma Care" computer software (a promotional system designed to assist health care practitioners in monitoring patients using Coumadin) to include warnings about switching to generic substitutes. (D.I. 1, ¶ 18 (98 Civ. 1695); D.I. 1, ¶ 35 (C.A.97-659))
- Defendant created and funded the Health Alliance for NTI Patient Safety to lobby state legislatures, formularies, and pharmacy boards to exclude NTI drugs from state generic substitution laws. (D.I. 1, ¶ 19 (98 Civ. 1695))
- Defendant initiated a publicity campaign touting Coumadin's "tighter than USP" content uniformity standards. (D.I. 1, ¶ 24 (98 Civ. 1695))
- Defendant issued a press release which contained the following assertions:

[i]f warfarin products are interchanged, patients should receive additional blood tests to ensure the amount of drug in their bloodstream is appropriate for their condition. It should be noted that this warning is included in the FDA-approved package insert for both [defendant's] Coumadin and for [plaintiff's] generic product.

* * *

[w]hile [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and the future health of over two million patients who depend on Coumadin everyday.

***4** (D.I. 1, ¶¶ 27, 31 (98 Civ. 1695) (citing defendant's press release of 7/28/97, at 2))

- Defendant offered for review to health care professionals a slide presentation in which defendant claimed that, regardless of FDA findings of bioequivalence, generic drugs may not be therapeutically equivalent to their branded counterparts. (D.I. 1, ¶ 29 (98 Civ. 1695))
- Defendant used the FDA's Adverse Drug Event ("ADE") reporting system in order to generate fear over switching from Coumadin to generic warfarin sodium. (D.I. 1, ¶ 35 (98 Civ. 1695)) Specifically, defendant issued a press release in which it stated that "it has submitted to the FDA more than 70 spontaneous reports from health care providers of adverse drug events temporally associated with patients who had been switched from one drug to the other." [FN8] (D.I. 1, ¶ 36 (98 Civ. 1695) (citing the press release of 12/3/97, at 1))

> FN8. Plaintiff contends that these ADE reports were rife with lies and mischaracterizations and were "designed to

> defame plaintiff both at the FDA and in the marketplace." (D.I. 13 at 13 (98 Civ. 1695)) Plaintiff alleges that some of these ADE reports did not even involve its generic warfarin sodium tablets. (D.I. 1, ¶ 38 (98 Civ. 1695)) Plaintiff further claims that defendant solicited a large number of reports or reported events that the health care providers in question did not consider "adverse events;" indeed, many health care providers were unaware of being credited with ADE reports. (D.I. 1, ¶¶ 39, 41, 42 (98 Civ. 1695))

The FDA admonished defendant for its assertions that additional blood testing was required following a switch from Coumadin to generic warfarin sodium. (D.I. 1, ¶ 28 (98 Civ. 1695)) For instance, in objecting to defendant's slide presentation, the FDA stated:

> It is misleading to suggest that generic products that FDA has determined are bioequivalent to Coumadin, may not be therapeutically equivalent to the reference product without substantial evidence to support such a claim. All FDA approved dosage forms of generic drugs classified as therapeutically equivalent ... can be substituted for the reference product with the full expectation that the substituted product will produce the same clinical effect and safety profile.

(D.I. 1, ¶ 29 (98 Civ. 1695) (citing FDA letter of 8/26/97, at 2))

In addition to its anticompetitive communications, defendant allegedly entered into a variety of anticompetitive rebate, "market retention" agreements, and "inventory management" agreements with pharmacy benefit managers, retail pharmacies, and pharmaceutical wholesalers in order to preserve its monopoly in the oral anticoagulant market. (D.I. 1, ¶¶ 53-62 (98 Civ. 1695)) According to plaintiff, defendant offered and paid rebates to pharmacy benefit managers [FN9] to ensure the dispensing of Coumadin rather than plaintiff's generic warfarin sodium. (D.I. 1, ¶ 54 (98 Civ. 1695)) It is alleged in this regard that defendant rewarded large pharmacy and drug store chains for stocking Coumadin as a substantial part of their oral anticoagulant inventory. (D.I. 1, ¶ 56 (98 Civ. 1695)) The "inventory management" agreements offered wholesalers "unprecedented rebates" and "extended payment terms" for purchases of specific quantities of Coumadin during July, August, and September of 1997. (D.I. 1, ¶ 59 (98 Civ. 1695)) Defendant allegedly timed these agreements to coincide with plaintiff's introduction of its generic warfarin sodium. (D.I. 1, ¶ 60 (98 Civ. 1695)) Defendant has offered similar "inventory management" incentives covering purchases in 1998. (D.I. 1, ¶¶ 60, 62 (98 Civ. 1695)) Plaintiff argues that these agreements have had the net effect of excluding its generic warfarin sodium from the oral anticoagulant market. (D.I. 1, ¶ 57 (98 Civ. 1695))

> FN9. Pharmacy benefit managers dictate which brands of pharmaceuticals will be dispensed to patients of managed care organizations and insurance companies. According to plaintiff, "almost three-quarters of all the prescriptions dispensed in this country are affected by such third-party adjudication." (D.I. 1, ¶ 54 (98 Civ. 1695))

III. POST-TRANSFER APPLICABLE LAW

***5** In the leading case on choice of law in multidistrict transfers, the District of Columbia Circuit Court has noted that "the law of a transferor forum on a federal question ... merits close consideration, but does not have stare decisis effect in a transferee forum situated in another circuit." *In re Korean Airlines Disaster,* 829 F.2d 1171, 1176 (D.C.Cir.1987), *aff'd on other grounds sub nom. Chan v. Korean Airlines Ltd.,* 490 U.S. 122, 109 S.Ct. 1676, 104 L.Ed.2d 113 (1989). In *In re Donald J. Trump Casino Sec. Litig.,* 7 F.3d 357 (3d Cir.1993), the Third Circuit assumed, without deciding, that the district court's adoption of the District of Columbia Circuit's rationale was proper. *See id.* at 367 n. 8. The Second Circuit also has held that a transferee federal court should apply its interpretations of federal law, not the transferor forum's constructions of federal law. *See Coker v.*

Pan Am. World Airways, Inc., 950 F.2d 839, 847 (2d Cir.1991) (concerning transfer motion pursuant to 28 U.S.C. § 157(b)(5)).

Accordingly, the court will apply Third Circuit precedent to the federal questions presented by these consolidated cases. Where no Third Circuit precedent exists, the court will give careful consideration to the law of the transferor forum. As for the state law issues presented in this case, the rule of *Van Dusen v. Barrack,* 376 U.S. 612, 84 S.Ct. 805, 11 L.Ed.2d 945 (1964), requires the court to apply the substantive state law of the jurisdiction in which the action was filed.

IV. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint, and it must construe the complaint in favor of the plaintiff. *See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.,* 140 F.3d 478, 483 (3d Cir.1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Id.* Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle it to relief. *See Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The moving party has the burden of persuasion. *See Kehr Packages, Inc. v. Fidelcor, Inc.,* 926 F.2d 1406, 1409 (3d Cir.1991). With these rules in mind, the court turns to an examination of the sufficiency of plaintiff's and class plaintiffs' complaints.

V. SUFFICIENCY OF PLAINTIFF'S COMPLAINT

Defendant argues that the court should dismiss plaintiff's monopolization and attempted monopolization claims. Further, defendant argues that its conduct does not state a claim under either the Lanham Act or under § 2(c) of the Robinson-Patman Act. Defendant also asserts that plaintiff has failed to allege the necessary elements of the state law business tort claims asserted against defendant. The court will address each of these issues in turn.

A. Plaintiff's Monopolization and Attempted Monopolization Claims

***6** Section 2 of the Sherman Act punishes "[e]very person who shall monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2 ("Sherman § 2"). The offense of monopolization under § 2 of the Sherman Act requires proof of: "(1) possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power, as distinguished from the growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.,* 384 U.S. 563, 570-71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966). In order to prevail on an attempted monopolization claim, a plaintiff must show "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v.. McQuillan,* 506 U.S. 447, 456, 113 S.Ct. 884, 122 L.Ed.2d 247 (1993).

Defendant does not dispute that it enjoys monopoly power in the market for oral anticoagulants. At issue is whether defendant's actions amount to predatory conduct or the willful acquisition of monopoly power. Defendant argues that its petitions to federal and state legislatures and administrative bodies, as well as its statements to health care providers and the general public, do not constitute predatory conduct because they enjoy immunity from antitrust liability under the *Noerr-Pennington* doctrine. Defendant also claims that such activity is not "exclusionary" under Sherman § 2.

1. The *Noerr-Pennington* Doctrine

In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.,* 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), the Supreme Court held

that concerted efforts to restrain or monopolize trade by petitioning the government enjoy antitrust immunity. *See also United Mine Workers v. Pennington,* 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) (holding that "[j]oint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). The Court has broadened *Noerr-Pennington* immunity to include the petitioning of the executive and judicial branches of government. [FN10] *See California Motor Transp. Co. v. Trucking Unlimited,* 404 U.S. 508, 513, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972). The Supreme Court generally has refused to impose antitrust liability for petitioning the government because doing so would infringe upon the First Amendment's protection of free speech, chill public involvement in our representative government, and impermissibly extend the Sherman Act to cover political as well as commercial activity. *See Noerr,* 365 U.S. at 137-38; *see also* 10 Earl W. Kintner & Joseph P. Bauer, *Federal Antitrust Law* § 77.1, at 187-88 (1994).

> FN10. The Supreme Court has extended *Noerr-Pennington* immunity as well to the petitioning of nongovernmental bodies when they perform quasi-public duties. *See Allied Tube & Conduit Corp. v. Indian Head, Inc.,* 486 U.S. 492, 108 S.Ct. 1931, 100 L.Ed.2d 497 (1988). The USP is a private entity, but it publishes the official compendium of pharmaceuticals in the United States. (D.I. 1, ¶ 24 (98 Civ. 1695)) Since the USP promulgates standards governing pharmaceuticals (through procedures similar to those used by administrative agencies), the court will analyze the defendant's petition to the USP as it would a petition before an administrative agency.

The Supreme Court has ruled, however, that frivolous and illegitimate petitioning of government bodies does not enjoy *Noerr-Pennington* immunity. In *City of Columbia v. Omni Outdoor Advertising, Inc.,* 499 U.S. 365, 111 S.Ct. 1344, 113 L.Ed.2d 382 (1991), the Court held that the "sham exception" to *Noerr-Pennington* immunity applies when "persons use the governmental process-- as opposed to the outcome of that process--as an anticompetitive weapon." *Id.* at 380. The Court has enunciated a two-part test to identify sham proceedings. *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,* 508 U.S. 49, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993) ("*PRE* ").

***7** The first prong of the test requires a court to determine [FN11] if the suit or proceeding is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 60. A suit is not objectively baseless if "an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome." *Id.* An antitrust plaintiff cannot prove a sham "merely by showing that its competitor's 'purposes were to delay [the plaintiff's] entry into the market." ' *Id.* at 59-60 (quoting *Omni Outdoor,* 499 U.S. at 381 (1991)).

> FN11. Plaintiff argues the "baselessness" inquiry is inherently a question of fact and, therefore, inappropriate for resolution by the court. (D.I. 13 at 15 (98 Civ. 1695)) The Supreme Court, however, has found that a court may decide, as a matter of law, whether a party invoking *Noerr-Pennington* immunity had probable cause to bring an allegedly baseless suit. *See PRE,* 508 U.S. at 63. A finding of probable cause "compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." *Id.*

Only if challenged litigation is "baseless" may courts examine the subjective motivations of the litigant. The second prong of the test invites courts to determine whether a defendant has anticompetitive motivations. Specifically, this second prong instructs courts to "focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor." ' *PRE,* 508 U.S. at 60-61 (quoting *Noerr,* 365 U.S. at 144)).

a. Defendant's Petition for Stay to the FDA

Plaintiff alleges that defendant's petition to the FDA was baseless in that it lacked expert testimony and evidentiary support. In support of its position, plaintiff quotes the former head of the FDA's Office of Generic Drugs as stating that defendant's Petition for Stay was "in the class of an economic challenge" rather than a scientific one. (D.I. 1, ¶ 23 (98 Civ. 1695)) Plaintiff complains that defendant's "maneuverings before the FDA delayed the introduction of [its] product by several months and imposed substantial additional costs on [it] and loss of sales revenue." (D .I. 1, ¶ 23 (98 Civ. 1695))

Other than conclusory allegations that defendant's petition lacked evidentiary support, plaintiff offers no basis for its assertion that defendant initiated its Petition for Stay without any "realistic expectation of success on the merits." *PRE,* 508 U.S. at 60. The complaint reveals that defendant's Petition for Stay proposed more stringent bioequivalency standards governing generic substitutes for Coumadin, but does not allege that defendant included fraudulent or misleading information in its Petition for Stay.

Without more, plaintiff cannot show that defendant's Petition for Stay lacked "a realistic expectation of success on the merits." *See PRE,* 508 U.S. at 60. Indeed, the complaint suggests that an objective litigant could conclude that defendant's Petition for Stay was "reasonably calculated to elicit a favorable outcome." *Id.* The complaint reveals that defendant petitioned the FDA for adoption of narrower bioequivalency standards--standards that the FDA had the exclusive power to set. In its ten page reply to the Petition for Stay, the FDA did not find the petition frivolous or unreasonable. Indeed, the FDA granted defendant's request that ANDA applicants be required to conduct certain tests unrelated to bioequivalency. Moreover, the FDA later proposed to adopt the very bioequivalency standards recommended by defendant in its Petition for Stay. *See* 62 Fed.Reg. 67880, 67881 (Dec. 17, 1997).

***8** The Supreme Court has recognized that "a successful 'effort to influence government action ... certainly cannot be characterized as a sham." ' *PRE,* 508 U.S. at 58 (quoting *Allied Tube,* 486 U.S. at 502). Plaintiff has failed to provide a basis for inferring that defendant's Petition for Stay was anything other than a successful attempt to secure more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant's motion to dismiss plaintiff's antitrust claim, as the claim relates to the Petition for Stay, is granted.

b. Defendant's Petition to the USP

Likewise, plaintiff's complaint is devoid of any facts from which the court could infer that defendant's USP petition lacked a "realistic expectation of success on the merits." *PRE,* 508 U.S. at 60. Plaintiff's complaint reveals only that defendant's petition requested a specific form of relief uniquely within the competence of the USP. Plaintiff presents no evidence that would support an inference of frivolousness or baselessness. Although the USP denied defendant's petition, the "court must resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE,* 508 U.S. at 61 n. 5 (internal quotations and citations omitted). Defendant's motion to dismiss plaintiff's antitrust claim, insofar as it is based on defendant's petition to the USP, is granted.

2. Defendant's Alleged Abuse of the FDA's ADE Reporting System

Plaintiff alleges that defendant submitted fraudulent ADE reports to the FDA and used these ADE reports in administrative hearings before state agencies. (D.I. 1, ¶¶ 38, 46 (98 Civ. 1695)) Defendant argues that these ADE reports, even if fraudulent, also enjoy *Noerr-Pennington* immunity. The Supreme Court, however, has declined to extend *Noerr-Pennington* immunity to deceptive practices before adjudicatory bodies like administrative agencies or courts. In *California Motor Transport,* the Court noted that "[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." *California Motor Transp.,*

404 U.S. at 513; *see also Allied Tube,* 486 U.S. at 500 (remarking that "in less political arenas, unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations"). Administrative agencies, like state pharmacy boards, act in an adjudicatory capacity when they consider petitions urging the adoption of stricter standards governing NTI drugs.

Accepting the facts contained in the complaint as true, the court can infer that defendant used fraudulent and misleading ADE reports before state administrative agencies. Supplying fraudulent information to state agencies "threatens the fair and impartial functioning of [such] agencies and does not deserve immunity from the antitrust laws." *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.,* 690 F.2d 1240, 1261 (9th Cir.1982). Insofar as plaintiff's Sherman § 2 claim rests on defendant's use of fraudulent ADE reports before state agencies, defendant's motion to dismiss is denied.

***9** Plaintiff's complaint also alleges that defendant used the ADE reports to urge state legislators to exclude generic warfarin sodium from state generic substitution laws. False statements made to legislators and legislative bodies in an effort to change government policy are protected by *Noerr-Pennington* immunity. In *Noerr,* the Court noted that deception in the political arena, "reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Noerr,* 365 U.S. at 145. False statements in the political arena enjoy antitrust immunity because "[t]here is an emphasis on debate in the political sphere, which can accommodate false statements and reveal their falsity." *Clipper Exxpress,* 690 F.2d at 1261. Consequently, plaintiff may not rest its monopolization claims on defendant's misrepresentations to state legislators or legislative bodies. [FN12]

> FN12. Plaintiff argues that the "commercial exception" to *Noerr-Pennington* immunity subjects defendant to antitrust liability for its misrepresentations to state legislatures that purchased pharmaceuticals for its citizens. Because neither the Second nor the Third Circuits have recognized the existence of this exception to *Noerr-Pennington* immunity and because the court has denied defendant's motion to dismiss on other grounds, the court declines to address the validity of plaintiff's "commercial exception" theory.

3. Defendant's Statements to the General Public and the Health Care Industry

Defendant argues that its statements to the general public and to the health care industry, even if false and misleading, are protected by the *Noerr-Pennington* doctrine because they were made as part of a campaign "to shape public policy regarding patient safety in the use of NTI drugs." (D.I. 12 at 10 (98 Civ. 1695)) Alternatively, defendant argues that its "statements of opinion" do not give rise to antitrust liability because they are not exclusionary conduct.

a. *Noerr-Pennington* Immunity

The Supreme Court has held that, where an anticompetitive restraint arises solely from private action, "the restraint cannot form the basis for antitrust liability if it is 'incidental' to a valid effort to influence government action." *Allied Tube,* 486 U.S. at 499 (citing *Noerr,* 365 U.S. at 143) (emphasis added)); *see also Massachusetts School of Law, Andover v. American Bar Ass'n,* 107 F.3d 1027, 1035 (3d Cir.1997) ("*MSL* "). The Supreme Court has recognized, however, that "[t]he validity of such efforts, and thus the applicability of *Noerr* immunity, varies with the context and nature of the activity." *Allied Tube,* 486 U.S. at 499.

The question at bar is whether defendant's public statements were incidental to valid efforts to persuade government agencies to adopt more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant argues that its public statements were "part and parcel" of its campaign to influence public officials and its

statements, even if false and misleading, enjoy *Noerr-Pennington* immunity. (*See* D.I. 12 at 10 (98 Civ. 1695))

Defendant's attempts to influence public officials centered on the establishment of stricter bioequivalency standards. In contrast, defendant's public statements warned consumers of "medical-legal" exposure in switching from Coumadin to generic warfarin sodium and urged doctors to conduct additional blood tests following a switch to generic warfarin sodium. (*See* D.I. 1, ¶ ¶ 18, 34 (98 Civ. 1695)) Defendant impugned the quality of plaintiff's generic warfarin sodium and issued press releases publicizing allegedly false ADE reports related to generic warfarin sodium. (*See* D.I. 1, ¶¶ 31, 46 (98 Civ. 1695))

***10** In *Noerr,* where the railroads published false and misleading public statements about the trucking industry, those statements were directly related to the railroads' efforts to obtain legislation regarding truck weight limits and increased taxes on heavy trucks. The railroads' publicity campaign addressed the damage done to highways by overweight trucks, the failure of the trucking industry to pay its fair share of road maintenance costs, and the hazards created by overweight trucks. *See Noerr,* 365 U.S. at 131. Indeed, the Supreme Court held that "at least insofar as the railroads's [publicity] campaign was directed toward obtaining governmental action, its legality was not at all affected by any anticompetitive purpose it may have had." *Id.* at 139-40 (emphasis added). In the case at bar, the court cannot infer at this stage of the proceedings that the totality of defendant's public statements were "part and parcel" of its efforts to secure more stringent bioequivalency standards for warfarin sodium drugs. For purposes of this motion to dismiss, therefore, the court finds that defendant's statements to the general public and to the health care community do not warrant *Noerr-Pennington* immunity.

b. Sherman § 2

Defendant cites *MSL* for the proposition that the Third Circuit has refused to construe false and misleading speech as exclusionary activity under Sherman § 2. In *MSL,* the Massachusetts School of Law argued that it was injured by the stigmatic effect of the ABA's refusal to accredit it. *See MSL,* 107 F.3d at 1037-38. It claimed this stigmatic effect arose from the ABA's attempts to convince states to make graduation from an ABA accredited law school necessary for bar admission. The law school characterized the ABA's efforts as a "campaign to convey the idea that ABA accreditation is the *sine qua non* of quality." *Id.* at 1037. In affirming the district court's granting of summary judgment in favor of the ABA, the court found that the complained-of speech amounted to nothing more than "the ABA's justification of its accreditation decisions." *Id.*

Unlike the facts in *MSL,* where the ABA was found merely to have defended its own standard setting and accreditation decisions, defendant's speech at issue is directed at consumers and directly attacks the quality and substitutability of plaintiff's generic warfarin sodium. The court finds the Third Circuit's decision in *MSL* inapposite under these circumstances.

Other courts have recognized that misleading advertising can rise to the level of anticompetitive conduct if the plaintiff "overcome[s] a presumption that the effect on competition of such a practice was *de minimis.*" *Berkey Photo, Inc. v. Eastman Kodak Co.,* 603 F.2d 263, 288 n. 41 (2d Cir.1979)(quoted in *National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.,* 850 F.2d 904, 916 (2d Cir.1988)). The Second Circuit, in a case factually similar to the one at bar, held that a plaintiff may overcome the *de minimis* bar (and a motion to dismiss) by "cumulative proof that [defendant's] representations were (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible of neutralization or other offset by rivals." *Ayerst Labs.,* 850 F.2d at 916. In the absence of Third Circuit precedent, the court finds these factors helpful in determining whether defendant's allegedly false and misleading statements rise to the level of unlawful exclusionary

conduct.

***11** In the present case, plaintiff's complaint satisfies each of the above six factors. The complaint alleges that defendant's extensive publicity campaign contained false misrepresentations. Plaintiff claims that these material misrepresentations were made to the general public in order to induce potential consumers to avoid purchasing generic warfarin sodium. On a motion to dismiss, plaintiff is entitled to the inference that the general public lacked the sophistication to discern that defendant's statements about bioequivalency were false. Although defendant argues that its statements were "readily susceptible to neutralization" by plaintiff and the FDA (D.I. 14 at 19-20) (98 Civ. 1695)), defendant is not entitled to this inference on a motion to dismiss. Moreover, plaintiff's dismal market share belies this assertion. (*See* D.I. 1, ¶ 16 (98 Civ. 1695)).

Consequently, the court finds that defendant's allegedly false and misleading speech had more than a *de minimis* effect on competition. Plaintiff may premise its Sherman § 2 claim on defendant's public statements.

4. Defendant's Rebate and Market Retention Agreements

Plaintiff claims that defendant's various rebate and market retention agreements also violate § 2 of the Sherman Act. Plaintiff argues that these agreements, in combination with defendant's misleading statements, have had the "synergistic effect" of harming competition in the oral anticoagulant market. (D.I. 13 at 27-29 (98 Civ. 1695)) Defendant contends that its price discounts and its allegedly deceptive statements "cannot possibly be viewed as working together 'synergistically' to produce an anticompetitive result because the theories of competitive harm are fundamentally at odds with each other." (D.I. 14 at 21 (98 Civ. 1695))

In analyzing an antitrust complaint, the court recognizes that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Continental Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962). The court finds that the combined effect of defendant's conduct could harm competition in the oral anticoagulant market. Those consumers that defendant failed to scare away from generic warfarin sodium could be "bought off" by defendant's rebate and inventory management incentives. Thus, defendant's allegedly misleading statements, coupled with financial disincentives to purchase generic warfarin sodium, could form part of an unlawful, multifaceted effort to hinder competition in the oral anticoagulant market.

In sum, plaintiff may premise its Sherman § 2 claim on defendant's use of allegedly fraudulent ADE reports before state agencies, defendant's allegedly false and misleading statements to the general public and the health care community, and defendant's use of rebates and market retention agreements as part of its allegedly multifaceted effort to restrain trade in the oral anticoagulant market. Plaintiff may not base its Sherman § 2 claim on defendant's petitions to the FDA or USP or defendant's use of allegedly fraudulent ADE reports before state legislatures.

B. Plaintiff's Lanham Act Claim

***12** Plaintiff claims that defendant violated § 43(a) of the Lanham Act by misrepresenting the nature, characteristics, and quality of plaintiff's product to "the public at large, wholesalers, pharmacies and health care professionals, as well as state and federal regulators." (D.I. 1, ¶ 73 (98 Civ. 1695)) The Lanham Act imposes civil liability on those who, "in commercial advertising or promotion, misrepresent[ ] the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services or commercial activities...." 15 U.S.C. § 1125(a)(1)(B) (emphasis added). The Act protects "consumers and competitors from a myriad of misrepresentations of products and services in commerce." *Wojnarowicz v. American Family Ass'n,* 745 F.Supp. 130, 141 (S.D.N.Y.1990) (quoting Allen v. National Video, Inc., 610 F.Supp.

612, 625 (S.D.N.Y.1985)).

Defendant contends that its public statements are immune from Lanham Act liability because they were not made in the context of "commercial advertising or promotion." Alternatively, defendant argues that, even if its statements occurred in the context of commercial advertising or promotion, its commercial speech was "inextricably intertwined" with protected First Amendment speech designed to influence public policies regarding warfarin sodium drugs. The court must determine whether defendant's public statements occurred "in commercial advertising or promotion" and, if so, whether those statements enjoy First Amendment protection from Lanham Act liability.

1. "In Commercial Advertising or Promotion"

There is a dearth of case law addressing whether a defendant's communications occurred "in commercial advertising or promotion." This is so because "[g]enerally, a plaintiff can easily satisfy its burden of proving that the complained-of representation was made in 'commercial advertising or promotion' by pointing to paid advertisements by a commercial defendant on television or radio, or in newspapers or magazines." *Gordon & Breach Science Publishers S .A. v. American Inst. of Physics,* 859 F.Supp. 1521, 1532 (S.D.N.Y.1994). Here, defendant's allegedly false and misleading statements did not appear in the classic form of an advertising campaign. Instead, they were made in the context of press releases, computer software, letters, and facsimile transmissions.

Courts that have addressed the "commercial advertising or promotion" issue have concluded that "the [Lanham] Act's reach is broader than the 'classic advertising campaign." ' *Seven-Up Co. v. Coca-Cola Co.,* 86 F.3d 1379, 1384 (5th Cir.1996) (quoting *Gordon & Breach,* 859 F.Supp. at 1534 (S.D.N.Y.1994)). Courts, for instance, have found § 43(a) applicable to the fundraising letters of a nonprofit pregnancy counseling group, *see Birthright v. Birthright, Inc.,* 827 F.Supp. 1114, 1137-38 (D.N.J.1993), and to an individual's "bad-mouthing" of her former company in telephone calls to friends and former colleagues, *see National Artists Management Co. v. Weaving,* 769 F.Supp. 1224, 1234-35 (S.D.N.Y.1991).

***13** The district court in *Gordon & Breach,* after an extensive analysis of case law and legislative history, distilled four factors necessary to satisfy the "commercial advertising or promotion" requirement of § 43(a)(1)(B). The statements must be

> (1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services ... (4) ... disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry.

Gordon & Breach, 859 F.Supp. at 1535-36; *accord Seven-Up Co. .,* 86 F.3d at 1384 (finding the district court's analysis "accurate and sound").

Applying this analysis to the facts at bar, defendant's statements satisfy at least three *Gordon & Breach* factors. Defendant competes with plaintiff in the oral anticoagulant market. Plaintiff sufficiently alleges that defendant's statements influenced doctors, pharmacists, and others to purchase or prescribe Coumadin instead of generic warfarin sodium. Defendant disseminated its statements to such a wide audience of the healthcare industry that plaintiff is entitled to the inference that defendant engaged in advertising or promotion. (*See, e.g.,* D.I. 1 at ¶ (alleging that defendant faxed a misleading letter to 45,000 pharmacists))

Turning to the final factor, the "commercial speech" requirement, the Supreme Court has defined "commercial speech" as "speech proposing a commercial transaction." *United States v. Edge Broad. Co.,* 509 U.S. 418, 426, 113 S.Ct. 2696, 125 L.Ed.2d 345 (1993); *see also Board of Trustees of State Univ. of N.Y. v. Fox,* 492 U.S. 469, 473-74, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989) (characterizing the proposal of a commercial transaction as "the test for identifying commercial speech") (emphasis added). [FN13] Defendant contends that none of its statements proposed any commercial transactions; rather, its statements conveyed merely "that care should be taken in

switching between warfarin products given warfarin sodium's status as an NTI drug." (D.I. 14 at 24) A review of plaintiff's complaint indicates that not all of defendant's statements are subject to such an innocuous interpretation.

> FN13. Defendant's petitions to the FDA, the USP, and those state agencies that merely set standards governing the bioequivalency of generic drugs do not fall within this definition. Plaintiff has not alleged, nor could it, that any statements made to these regulatory bodies proposed a commercial transaction.

For instance, defendant's "Couma Care" computer software included praise for the "high quality" of Coumadin while warning of the "risks" and "medical-legal exposure" entailed in switching from Coumadin to generic warfarin sodium. (D.I. 1, ¶ 18 (98 Civ. 1695)) In a press release coinciding with the introduction of plaintiff's warfarin sodium tablets, defendant claimed that "while [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and the future health of over two million patients who depend on Coumadin everyday." (D.I. 1, ¶ 31 (98 Civ. 1695)) Defendant also allegedly employed false ADE reports to dissuade pharmacists and state pharmacy boards from purchasing plaintiff's generic warfarin sodium.

***14** Statements such as these satisfy the court that defendant's press releases and other communications were not confined solely to defendant's efforts to influence public policy on generic substitution of warfarin sodium drugs. Plaintiff at this stage of the proceedings is entitled to the inference that defendant's statements "proposed a commercial transaction" by (1) denigrating plaintiff's generic warfarin sodium, (2) stressing the dangers of substituting generic warfarin sodium for Coumadin, and (3) touting Coumadin's "high quality" and "tighter than USP" content uniformity specifications. (*See* D.I. 1, ¶¶ (98 Civ. 1695))

In order to state a *prima facie* case under § 43(a) of the Lanham Act, the Third Circuit has ruled that a plaintiff must show

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods travelled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of goodwill, etc.

U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922- 23 (3d Cir.1990) (quoting *Max Daetwyler Corp. v. Input Graphics, Inc.,* 545 F.Supp. 165, 171 (E.D.Pa.1982)). Consistent with its findings above, the court finds that plaintiff has satisfied each element of its *prima facie* case.

Nonetheless, the court still must determine whether defendant's commercial speech enjoys First Amendment protection. Defendant contends that its statements are "inextricably intertwined" with protected political speech and, consequently, all of its communications are entitled to full First Amendment protection. Defendant relies heavily on the Supreme Court's decision in *Riley v. National Federation of the Blind,* 487 U.S. 781, 108 S.Ct. 2667, 101 L.Ed.2d 669 (1988). In *Riley,* the Court assessed the constitutionality of a North Carolina statute which required solicitors of charitable contributions to divulge to potential donors the percentage of the previous year's donations that actually went to charities. In deciding that it would apply strict scrutiny analysis to the statute, the Court noted that "where, as here, the component parts of a single speech are inextricably intertwined, we cannot parcel out the speech, applying one [standard of review] test to one phrase and another test to another phrase." *Id.* at 796.

The Court revisited the issue of "inextricably intertwined" speech in *Fox. See* 492 U.S. 469, 109 S.Ct. 3028, 106 L.Ed.2d 388. In *Fox,* the Court reviewed the constitutionality of a state university regulation that prohibited private commercial enterprises in student dormitory rooms. The Court

distinguished its holding in *Riley* by finding that the essentially commercial "Tupperware parties" involved in *Fox* did not enjoy full First Amendment immunity from state regulation--even though the commercial activity at issue in *Fox* combined "sales pitches" with lectures on home economics, personal finance, and other protected forms of "pure" speech. Writing for the Court, Justice Scalia explained that in *Riley,*

> ***15** the commercial speech (if it was that) was "inextricably intertwined" because the state law required that it be included. By contrast, there is nothing whatever "inextricable" about the noncommercial aspects of these ["Tupperware"] presentations. No law of man or of nature makes it impossible to sell housewares without teaching home economics, or to teach home economics without selling housewares.

Fox, 492 U.S. at 474.

Defendant fails to appreciate the Supreme Court's distinction between the protected "inextricably intertwined" speech in *Riley* and the unprotected "voluntarily intertwined" speech in *Fox.* In the case at bar, defendant voluntarily interspersed its protected speech relating to heightened standards for warfarin sodium drugs with comments about plaintiff's product, which comments are alleged to be false and misleading. Nothing required defendant to mislead consumers and disparage plaintiff's product while expressing its protected opinions on the standards governing warfarin sodium.

Thus, defendant's commercial speech is not "inextricably intertwined" with its protected speech. Because false and misleading commercial speech does not enjoy First Amendment protection, [FN14] defendant's statements are subject to Lanham Act scrutiny. Defendant's motion to dismiss plaintiff's Lanham Act claim is denied.

> FN14. Commercial speech, when found to be false and misleading, "is not protected by the First Amendment at all." *City of Cincinnati v. Discovery Network, Inc.,* 507 U.S. 410, 434, 113 S.Ct. 1505, 123 L.Ed.2d 99 (Blackmun, J., concurring). Commercial speech enjoys "less protection ... than ... other constitutionally safeguarded forms of expression", *Bolger v. Youngs Drug Prods. Corp.,* 463 U.S. 60, 64-65, 103 S.Ct. 2875, 77 L.Ed.2d 469 (1983), because "there is greater potential for deception or confusionin the context of certain advertising messages." *Id.* at 65. Moreover, commercial speech is marked by "greater objectivity and hardiness ... [which] may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 771 n. 24, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976).

C. Plaintiff's Robinson-Patman Claim

Section 2(c) of the Robinson-Patman Act reads, in relevant part:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant ... anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods ... either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c). Congress enacted this section in order to combat the use of "dummy" brokerage fees as a means of securing unlawful price rebates. The Supreme Court has found the language of § 2(c) applicable to commercial bribery. *See FTC v. Henry Broch & Co.,* 363 U.S. 166, 169 n. 6, 80 S.Ct. 1158, 4 L.Ed.2d 1124 (1960) ("the debates on the bill show clearly that § 2(c) was intended to proscribe other practices such as the 'bribing' of a seller's broker by the buyer") (dictum). Commercial bribery is an aspect of "the classic arrangement that § 2(c) aimed to eliminate--a situation where the fiduciary of one party is influenced by another party

to the transaction by the payment of brokerage when no services are performed." *Yeager's Fuel, Inc. v. Pennsylvania Power & Light Co.,* 953 F.Supp. 617, 665 (E.D.Pa.1997); *accord Harris v. Duty Free Shoppers Ltd.,* 940 F.2d 1272, 1274 & n. 3 (9th Cir.1991). With respect to commercial bribery, the Third Circuit has required the plaintiff to show that "the illegal payments in question crossed the line from buyer to seller or vice versa." *See Environmental Tectonics v. W.S. Kirkpatrick, Inc.,* 847 F.2d 1052, 1066 (3d Cir.1988) (citing *Seaboard Supply Co. v. Congoleum Corp.,* 770 F.2d 367, 372 (3d Cir.1985)).

***16** Defendant argues that plaintiff has failed to allege that the financial incentives offered by defendant constituted unlawful bribes to fiduciaries of Coumadin purchasers. (D.I. 12, at 25-26 (98 Civ. 1695)) In its complaint, plaintiff alleges that defendant paid rebates and/or "administrative fees" to pharmacy benefit managers, managed care companies, retail pharmacies, and pharmacy wholesalers. (D.I. 1, ¶¶ 53, 56, 57, 59 (98 Civ. 1695)) Plaintiff explains that pharmacy benefit managers act as fiduciaries for managed care companies, insurance companies, and others who employ them to broker cost-effective deals with pharmaceutical sellers. Plaintiff claims that these rebates and fees were designed to exclude its generic warfarin sodium from the anticoagulant market. (D.I. 1, at ¶ 53 (98 Civ. 1695)) Plaintiff further alleges that these payments were not made in exchange for any services rendered in connection with the sale of Coumadin. (D.I. 1, ¶¶ 53, 58 (98 Civ. 1695))

At this stage of the proceedings plaintiff's complaint permits the inference that defendant unlawfully bribed these pharmacy benefit managers as well as the ultimate purchasers of Coumadin. Because these rebates were never offered by defendant until the introduction of generic warfarin sodium (D.I. 1, ¶ 61 (98 Civ. 1695)), the court can also infer that these financial incentives were offered in order to exclude generic warfarin sodium from the oral anticoagulant market. As such, plaintiff has stated a claim of commercial bribery under § 2(c) of the Robinson-Patman Act.

D. Plaintiff's New York General Business Law Claims

Count V of the complaint alleges that defendant's false and misleading statements violated §§ 349 and 350 of the New York General Business Law. Section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. L. § 349 (McKinney 1997). Section 350 states that "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." *Id.* § 350. In an action brought under either section, the plaintiff must show "(i) that the act or practice was misleading in a material respect, and (ii) that the plaintiff was injured." *Coors Brewing Co. v. Anheuser-Busch Cos.,* 802 F.Supp. 965, 975 (S.D.N.Y.1992). Although the New York legislature enacted the statute as a consumer protection measure, *see Genesco Entertainment v. Koch,* 593 F.Supp. 743, 751 (S.D.N.Y.1984), "corporate competitors now have standing to bring a claim under this [statute] ... so long as some harm to the public at large is at issue." *Bristol-Myers Squibb Co. v. McNeill-P.P.C., Inc.,* 786 F.Supp. 182, 215 (E.D.N.Y.), *vacated in part on other grounds,* 973 F.2d 1033 (2d Cir.1992). "The critical question, then, is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor." *Securitron Magnalock Corp. v. Schnabolk,* 65 F.3d 256, 264 (2d Cir.1995).

***17** In its supporting brief, defendant reiterates its claim that its public statements enjoy First Amendment immunity and, therefore, cannot serve as grounds for liability under the New York General Business Law. (D.I. 12 at 28 n. 9 (98 Civ. 1695)) Consistent with the findings above that at least some of defendant's speech is not protected by the First Amendment, the court further finds that plaintiff has alleged materially false and misleading statements by the defendant that harmed purchasers of anticoagulant drugs. Therefore, the plaintiff has stated a claim for relief under §§ 349 and 350 of the New York General Business Law. Defendant's motion to dismiss these claims is denied.

E. Plaintiff's New York Common Law Claims

In Count VI of its complaint, plaintiff alleges that defendant's false statements constituted common law trade disparagement. "Trade libel or product disparagement is an action to recover for words or conduct which tend to disparage or negatively reflect upon the condition, value or quality of a product or property." *Angio-Medical Corp. v. Eli Lilly & Co.,* 720 F.Supp. 269, 274 (S.D.N.Y.1989). In order to prove product disparagement the plaintiff must plead and prove "(1) falsity of the statement, (2) publication to a third person, (3) malice (express or implied), and (4) proven special damages." *Id.* New York courts have defined special damages as "the pecuniary loss resulting directly from the effect of a defendant's allegedly wrongful conduct." *Charles Atlas, Ltd. v. Time-Life Books, Inc.,* 570 F.Supp. 150, 155 (S.D.N.Y.1983); *see also Angio-Medical Corp.,* 720 F.Supp. at 274 (describing special damages as the "natural and immediate consequence of the disparaging statements"). Loss of sales is a proper item of special damages. *See Charles Atlas, Ltd.,* 570 F.Supp. at 155.

In the case at bar, plaintiff sufficiently alleges that defendant's numerous public comments were malicious and that they disparaged the quality of plaintiff's generic warfarin sodium. Defendant argues that plaintiff has failed to properly plead special damages because plaintiff has not specified the particular customers with whom it would have done business but for defendant's disparaging statements. While defendant rightly notes that some New York courts have required such specificity, at least one New York court has recognized the need for a more liberal approach in cases where it is "virtually impossible to identify those who did not order the plaintiff's product" because "such people would simply have failed to order, thus leaving no record of their identity." *Charles Atlas, Ltd.,* 570 F.Supp. at 156 (citing William Prosser, *Handbook of the Law of Torts* § 128, at 921-22 (4th ed.1971); *see also Teilhaber Mfg. Co. v. Unarco Materials Storage,* 791 P.2d 1164, 1167 (Colo.Ct.App.1989).

Plaintiff has not cited the specific customers it lost because of defendant's allegedly false and misleading statements. Plaintiff, however, has alleged that its market share in the oral anticoagulant market has suffered because of defendant's allegedly misleading publicity campaign. At this stage of the proceedings, the court finds that plaintiff has pled special damages with sufficient particularity. Given the mass dissemination of defendant's allegedly false and misleading statements, the court finds that demanding more specificity from plaintiff at this early stage in the litigation would be unfair and inappropriate.

***18** Count VII of plaintiff's complaint alleges tortious interference with prospective business relations. In order to prevail on such a claim, "a plaintiff must demonstrate that the defendant interfered with business relations existing between a plaintiff and a third party, either with the purpose of harming the plaintiff or by means that are dishonest, unfair, or improper." *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council,* 857 F.2d 55, 74 (2d Cir.1988). A cause of action for tortious interference with prospective business advantage "applies to those situations where the third party would have entered into or extended a contractual relationship with plaintiff but for the intentional and wrongful acts of the defendant." *M.J. & K. Co. v. Matthew Bender & Co.,* 220 A.D.2d 488, 631 N.Y.S.2d 938, 940 (N.Y.App.Div.1995) (quoting *WFB Telecomms., Inc. v. NYNEX Corp.,* 188 A.D.2d 257, 590 N.Y.S.2d 460, 461 (N.Y.App.Div.1992)).

In the present case, plaintiff alleges that, due to defendant's false and misleading statements, pharmacy benefit managers, managed care companies, and others refused to purchase plaintiff's generic warfarin. The facts reveal that these entities normally prefer less expensive generic drugs to branded pharmaceuticals. At this stage of the proceedings, plaintiff is entitled to the inference that, but for defendant's false and misleading statements, these third parties would have entered into contracts with plaintiff. Plaintiff has presented sufficient factual support to state a claim for relief under common law tortious interference with

prospective business advantage. Defendant's motion to dismiss is denied.

VI. SUFFICIENCY OF CLASS PLAINTIFFS' COMPLAINTS

Class plaintiffs' antitrust complaints are identical: they seek treble damages and injunctive relief under §§ 4 and 16 of the Clayton Act for allegedly supracompetitive prices charged for Coumadin by defendant. Class plaintiffs' factual summaries of defendant's alleged violations of Sherman § 2 mirror plaintiff's complaint. The court will address class plaintiffs' antitrust claims as a whole. Class plaintiff Tischler also alleges that defendant's actions violate the Florida Deceptive and Unfair Trade Practices Act ("DUTPA"). Fla. Stat. Ann. §§ 501.201 *et seq.* Class plaintiff Steckel additionally alleges several Pennsylvania state law claims.

A. Class Plaintiffs Lack Antitrust Standing

Class plaintiffs seek treble damages under § 4 of the Clayton Act [FN15] for the allegedly supracompetitive prices charged for Coumadin by defendant. Citing the Supreme Court's decision in *Illinois Brick Co. v. Illinois,* 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), defendant argues that class plaintiffs lack antitrust standing because they are indirect purchasers of Coumadin. Class plaintiffs argue that the "bright-line" rule of *Illinois Brick* does not bar their claim because the Supreme Court has enunciated a broader antitrust standing test in *Associated General Contractors, Inc. v. California State Council of Carpenters,* 459 U.S. 519, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983) ("*AGC* "). The court finds that even under the more flexible balancing test of *AGC,* class plaintiffs still lack antitrust standing.

> FN15. Section 4 of the Clayton Act provides, in pertinent part, that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court ... and shall recover threefold the damages by him sustained...." 15 U.S.C. § 15(a).

***19** In *AGC,* the Supreme Court synthesized its previous rulings on antitrust standing by analyzing five factors to resolve the standing issue before it. As the Third Circuit explained in *McCarthy v. Recordex Serv., Inc.,* 80 F.3d 842, 850 (3d Cir.1996), the Supreme Court considered (1) the causal connection between the antitrust violation and the harm to the plaintiff, (2) whether the antitrust injury is "of the type that the antitrust statute was intended to forestall," (3) the directness or indirectness of the asserted injury, (4) the existence of more direct victims of the alleged violation, and (5) the potential for duplicative recovery or complex apportionment of damages. *See id.* at 850 (citing *AGC,* 459 U.S. at 537- 44).

These factors, when applied to the facts at bar, weigh heavily against class plaintiffs. Factors one and three require class plaintiffs to show that defendant's monopolization of the oral anticoagulant market directly caused their injuries. Although class plaintiffs assert that they were forced to pay supracompetitive prices, their ability to trace this effect to the alleged anticompetitive conduct traverses "several somewhat vaguely defined links." *AGC,* 459 U.S. at 540.

In their complaints, class plaintiffs assert that class members may be identified from records maintained by pharmacies, drugstores, and managed care companies. (D.I. 1, ¶ 7 (C.A.97-659)) This demonstrates that class plaintiffs purchased Coumadin from intermediaries rather than from defendant. Each of these organizations purchased their supplies of Coumadin from pharmaceutical wholesalers. (D.I. 8 at 11 (C.A.97-659)) Class plaintiffs, then, are third in the distribution chain of Coumadin. Although class plaintiffs do not discuss third party payor arrangements, it is almost certain that most of the 1.8 million class members had some sort of health insurance. More often than not, third party payors actually "pay" for the cost of prescriptions while patients pay only a yearly premium (some of which might be subsidized by the patient's employer). Other third party payor arrangements reimburse patients for part or all of the price paid for the prescription.

In sum, this case presents a classic indirect purchaser scenario. It is unclear from the complaints whether class plaintiffs suffered any antitrust injury at all. Any injuries actually suffered by class plaintiffs are too remote to justify antitrust standing.

Turning to the fourth *AGC* factor, the remoteness of class plaintiffs' injuries also points to the existence of more direct victims of defendant's allegedly unlawful conduct. If defendant's monopolization of the oral anticoagulant market resulted in supracompetitive prices for Coumadin, the insurance companies and third party payor organizations most likely absorbed some or all of that overcharge. Those organizations, and not more remote victims like class plaintiffs, are the proper parties to bring suit to recover the overcharge.

***20** The fifth factor of the *AGC* analysis concerns the potential for duplicative recovery or complex apportionment of damages. Allowing class plaintiffs to proceed in the present case would expose defendant to multiple recoveries in antitrust actions brought by those more directly injured by its conduct. Moreover, the sheer variety of third party payor plans would render the apportionment of damages among the class plaintiffs incredibly complex. A trier of fact would have to ascertain the percentage of the overcharge actually suffered by each class plaintiff. This figure would vary from plaintiff to plaintiff due to the involvement of third party payors and other intermediary purchasers--some of which may or may not have absorbed the alleged overcharge. The apportionment problem is magnified by the fact that class plaintiffs purport to represent 1.8 million consumers of Coumadin.

The court concludes that class plaintiffs have not adequately alleged antitrust injury. As the Supreme Court has recognized, "[a]n antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but 'despite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable.' " *Blue Shield of Va. v. McCready,* 457 U.S. 465, 476-77, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982) (citing *Illinois Brick,* 431 U.S. at 760 (Brennan, J., dissenting)). Class plaintiffs at bar lack antitrust standing, and defendant's motion to dismiss their Sherman § 2 claims is granted.

B. Injunctive Relief

Class plaintiffs seek injunctive relief from defendant's alleged monopolistic practices under § 16 of the Clayton Act. Section 16 provides, in relevant part, that "[a]ny person ... shall be entitled to sue for and have injunctive relief ... against threatened loss or damage by a violation of the antitrust laws...." 15 U.S.C. § 26. The Supreme Court has held that "in order to seek injunctive relief under § 16, a private plaintiff must allege threatened loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendant['s] acts unlawful.' " *Cargill, Inc. v. Monfort of Colo., Inc.,* 479 U.S. 104, 113, 107 S.Ct. 484, 93 L.Ed.2d 427 (1986) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.,* 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977)). The Court remarked in *Cargill* that it would be "anomalous ... to read the Clayton Act to authorize a private plaintiff to secure an injunction against a threatened injury for which he would not be entitled to compensation if the injury actually occurred." *Id.* at 112. *See also West Penn Power Co.,* 147 F.3d at 264 (holding that "when seeking injunctive relief [under the Clayton Act], 'the complainant need only demonstrate a significant threat of injury from an impending violation of the antitrust laws.' ') (emphasis added & citation omitted).

In the present case, class plaintiffs have not sufficiently alleged either antitrust injury or a causal connection between defendant's allegedly unlawful activity and their purported injury. Thus, class plaintiffs have failed to allege injury of the type the Sherman Act was designed to prevent. Therefore, class plaintiffs do not have standing to assert injunctive relief under § 16 of the Clayton Act.

C. Class Plaintiffs' State Law Claims

***21** Because the court has dismissed class

plaintiffs' federal claims, the only claims remaining arise out of state statutes and state common law. Pursuant to 28 U.S.C. § 1367(c)(2)-(3), the court declines to exercise supplemental jurisdiction over these state claims because state law issues substantially predominate over the now dismissed federal claims. Therefore, the court grants defendant's motions to dismiss class plaintiffs' complaints.

VII. CONCLUSION

For the reasons stated, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted. An order shall issue consistent with this memorandum opinion.

Not Reported in F.Supp.2d, 1998 WL 883469 (D.Del.), 1999-1 Trade Cases P 72,457

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